IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

CANDELA CORPORATION, *Plaintiff*, v. PALOMAR MEDICAL TECHNOLOGIES, INC. *Defendant.*	**MISCELLANEOUS DOCKET NO.** _____ 08CV949 JUDGE NORGLE MAG. JUDGE DENLOW

NOTICE OF FILING

To: (See Attached Service List)

PLEASE TAKE NOTICE that we filed with the Clerk of the United States District Court for the Northern District of Illinois, on February 12, 2008, **Notice of Motion, Plaintiffs' Motion to Compel Dr. Stanley Kovak to Produce Subpoenaed Documents, Notice of Filing, and Civil Cover Sheet**, copies of which are attached hereto and herewith served upon you.

DATED: February 12, 2008

Respectfully submitted,

Robert A. Cote
New York State Bar No. 2331957
MCKOOL SMITH P.C.
399 Park Avenue, Suite 3200
New York, NY 10022
Telephone: (212) 402-9402
Telecopier: (212) 402-9444
rcote@mckoolsmith.com
One of the attorneys for Plaintiff

Pierre Hubert
Texas State Bar No. 24002317
phubert@mckoolsmith.com
Craig Tolliver

Texas State Bar No. 24028049
ctolliver@mckoolsmith.com
John M. Shumaker
Texas State Bar No. 24033069
jshumaker@mckoolsmith.com
MCKOOL SMITH P.C.
300 W. 6th Street, Suite 1700
Austin, Texas 78701
Telephone: (512) 692-8700
Telecopier: (512) 692-8744

SERVICE LIST

DEFENDANT PALOMAR MEDICAL TECHNOLOGIES, INC.

David J. Beck, Esq.
Timothy A. Cleveland
BECK REDDEN & SECREST L.L.P.
One Houston Center
1221 McKinney Street, Suite 4500
Houston , TX 77010-2020
Tel.: (713) 951-3700

Debra D. Nye
FOLEY & LARDNER LLP
11250 El Camino Real, Suite 200
San Diego , CA 92130
Tel.: (858) 847-6730

John T Gutkoski
Michelle A. Flores
Stephen D. Riden
FOLEY & LARDNER, LLP
111 Huntington Ave
Boston , MA 02199
Tel.: (617) 342-4000

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

CANDELA CORPORATION, *Plaintiff,* v. PALOMAR MEDICAL TECHNOLOGIES, INC. *Defendant.*	§	Civil Action No. 9-06-CV-277-RHC (United States District Court for the Eastern District of Texas - Lufkin Division) 08CV949 JUDGE NORGLE MAG. JUDGE DENLOW

DECLARATION OF CRAIG N. TOLLIVER IN SUPPORT OF PLAINTIFFS' MOTION TO COMPEL DR. STANLEY KOVAK TO PRODUCE SUBPOENAED DOCUMENTS

I, Craig N. Tolliver, declare as follows:

1. I am an associate at the law firm McKool Smith, P.C., attorneys of record for Plaintiffs Candela Corporation ("Candela") and The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH") in the above-referenced matter pending in the United States District Court for the Eastern District of Texas. I am over the age of twenty-one (21). I have personal knowledge of the following facts and statements in this declaration and, if called upon to testify, I could and would testify competently thereto.

2. Attached hereto as **Exhibit 1** is a true and correct copy of Plaintiffs' Second Amended Complaint for Patent Infringement, filed July 13, 2007.

3. Attached hereto as **Exhibit 2** is a true and correct copy of a Subpoena in a Civil Case to Dr. Stanley Kovak, dated December 4, 2007.

4. Attached hereto as **Exhibit 3** is a true and correct copy of Objections to Subpoena to Dr. Stanely Kovak, dated December 14, 2007.

5. Attached hereto as **Exhibit 4** is a true and correct copy of a letter from C. Tolliver to John Gutkoski, dated December 24, 2007.

6. Attached hereto as **Exhibit 5** is a true and correct copy of a letter from Stephen Riden to C. Tolliver, dated January 11, 2008.

7. Attached hereto as **Exhibit 6** is a true and correct copy of an excerpt from the transcript of the Case Management Conference, dated March 23, 2007.

8. Attached hereto as **Exhibit 7** is a true and correct copy of an excerpt from Defendant Palomar Medical Technologies, Inc.'s Claim Construction Brief.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct. Executed on January 22, 2008 in Austin, Texas.

Craig N. Tolliver

Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

CANDELA CORPORATION, *Plaintiff,*	§	
v.	§	Civil Action No. 9-06-CV-277
PALOMAR MEDICAL TECHNOLOGIES, INC.	§	**JURY TRIAL DEMANDED**
Defendant.	§	

PLAINTIFFS' SECOND AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Candela Corporation ("Candela") and The General Hospital Corporation d/b/a Massachusetts General Hospital ("MGH"), by their attorneys McKool Smith, P.C., bring this action for patent infringement against Palomar Medical Technologies, Inc. ("Palomar") and allege as follows:

Parties

1. Plaintiff Candela is a corporation organized and existing under the law of the State of Delaware and has its corporate headquarters at 530 Boston Post Road, Wayland, MA 01778.

2. Plaintiff Candela is the market leader in the development, manufacturing and distribution of medical and aesthetic laser and light-based technologies. Candela's product line is the most comprehensive and technologically sophisticated line of aesthetic laser and light-based systems in the world. Candela's products are used for such applications as wrinkle reduction, skin tightening and rejuvenation.

3. Plaintiff MGH is a duly incorporated Massachusetts non-profit charitable hospital. MGH is a teaching hospital of Harvard Medical School as well as a biomedical research facility. Its corporate address is 55 Fruit Street, Boston, Massachusetts, 02114.

4. On information and belief, Defendant Palomar is also a corporation organized and existing under the law of the State of Delaware and conducts business in the State of Texas.

5. On information and belief, Defendant Palomar produces pulsed light infrared and laser systems for aesthetic applications such as wrinkle reduction, skin tightening and rejuvenation.

Jurisdiction and Venue

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 et seq. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202.

7. Upon information and belief, the Court has personal jurisdiction over Defendant Palomar because it is a corporation that regularly conducts business, and has committed acts of infringement complained of herein, within the State of Texas and within this judicial district.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c) and 1400.

COUNT I

Palomar's Infringement of the '801 Patent

9. The allegations of paragraphs 1 through 8 are incorporated by reference into this Count I as though fully set forth herein.

10. Candela is an assignee of and has the exclusive rights to U.S. Patent No. 5,810,801 ("the '801 patent"). MGH is also an assignee of the '801 patent.

11. The '801 patent, a true and correct copy of which is attached hereto as **Exhibit A**, was duly issued by the United States Patent and Trademark Office, and is valid and enforceable.

12. The '801 patent describes methods and apparatuses for wrinkle treatment and skin rejuvenation.

13. On information and belief, Palomar makes, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, products that have infringed and/or continue to infringe, either literally or by equivalents, contribute to the infringement of, and/or induce the infringement of one or more claims of the '801 patent, including at least Palomar's Lux1540™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's Lux1540-Z™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's LuxIR™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's LuxDeepIR™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's Lux B™ handpiece combined with any of the StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems, MediLux™ series systems or EsteLux™ series systems; and Palomar's Lux G™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems, MediLux™ series systems or EsteLux™ series systems.

14. On information and belief, this infringing activity has been, and continues to be done, with knowledge of the '801 patent, and is willful conduct which would result in enhanced damages under 35 U.S.C. § 284.

15. Plaintiffs have been, and are being, irreparably harmed, and incurred, and will continue to incur, damages as a result of Palomar's willful infringement of the '801 patent.

COUNT II

Palomar's Infringement of the '497 Patent

16. The allegations of paragraphs 1 through 15 are incorporated by reference into this Count II as though fully set forth herein.

17. Candela is an assignee of and has the exclusive rights to U.S. Patent No. 6,120,497 ("the '497 patent"). MGH is also an assignee of the'497 patent.

18. The '497 patent, a true and correct copy of which is attached hereto as **Exhibit B,** was duly issued by the United States Patent and Trademark Office, and is valid and enforceable.

19. The '497 patent describes methods for wrinkle treatment and skin rejuvenation.

20. On information and belief, Palomar makes, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, products that have infringed and/or continue to infringe, either literally or by equivalents, contribute to the infringement of, and/or induce the infringement of one or more claims of the '497 patent, including at least Palomar's Lux1540™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's Lux1540-Z™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's LuxIR™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's LuxDeepIR™ handpiece combined with a Star®Lux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's Lux B™ handpiece combined with any of the StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems, MediLux™ series systems or EsteLux™ series systems; and Palomar's Lux G™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems, MediLux™ series systems or EsteLux™ series systems.

21. On information and belief, this infringing activity has been, and continues to be done, with knowledge of the '497 patent, and is willful conduct which would result in enhanced damages under 35 U.S.C. § 284.

22. Plaintiffs have been, and are being, irreparably harmed, and incurred, and will continue to incur, damages as a result of Palomar's willful infringement of the '497 patent.

COUNT III

Palomar's Infringement of the '999 Patent

23. The allegations of paragraphs 1 through 22 are incorporated by reference into this Count III as though fully set forth herein.

24. Candela is an assignee of and has the exclusive rights to U.S. Patent No. 6,659,999 ("the '999 patent"). MGH is also an assignee of the '999 patent.

25. The '999 patent, a true and correct copy of which is attached hereto as **Exhibit C**, was duly issued by the United States Patent and Trademark Office, and is valid and enforceable.

26. The '999 patent describes methods for wrinkle treatment and skin rejuvenation.

27. On information and belief, Palomar makes, uses, offers to sell, and/or sells within the United States, and/or imports into the United States, products that have infringed and/or continue to infringe, either literally or by equivalents, contribute to the infringement of, and/or induce the infringement of one or more claims of the '999 patent, including at least Palomar's Lux1540™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's Lux1540-Z™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's LuxIR™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems; Palomar's LuxDeepIR™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems;

Palomar's Lux B™ handpiece combined with any of the StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems, MediLux™ series systems or EsteLux™ series systems; Palomar's Lux G™ handpiece combined with any of the StarLux® series system, including but not limited to the StarLux® or StarLux® 500 systems, MediLux™ series systems or EsteLux™ series systems and Palomar's Lux Y™ handpiece combined with a StarLux® series system, including but not limited to the StarLux® 500 or StarLux™ series systems, MediLux™ series systems or EsteLux™ series systems.

28. On information and belief, this infringing activity has been, and continues to be done, with knowledge of the '999 patent, and is willful conduct which would result in enhanced damages under 35 U.S.C. § 284.

29. Plaintiffs have been, and are being, irreparably harmed, and incurred, and will continue to incur, damages as a result of Palomar's willful infringement of the '999 patent.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Palomar as follows:

(a) Declaring that Palomar has infringed, directly, or indirectly, literally or by means of the doctrine of equivalents, one or more claims of the '801, '497, and '999, patents (collectively, the "Candela Patents");

(b) Ordering that Palomar, its officers, agents, servants, employees, attorneys, and all other persons in active concert or participation with Palomar, be permanently enjoined and restrained from further infringing the Candela patents;

(c) Awarding Plaintiffs all relief available under the patent laws of the United States, including but not limited to monetary damages, including prejudgment interest and enhanced damages based on Palomar's willful infringement of the Candela patents;

(d) Awarding Plaintiffs their costs and reasonable attorneys fees in respect thereto in accordance with 35 U.S.C. §§ 284-85; and

(e) Granting Plaintiffs such other relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: July 13, 2007.

McKOOL SMITH, P.C.

By: /s/ Sam Baxter
Sam Baxter, Lead Attorney
Texas State Bar No. 01938000
sbaxter@mckoolsmith.com
P.O. Box O
505 E. Travis, Suite 105
Marshall, Texas 75670
Telephone: (903) 927-2111
Telecopier: (903) 927-2622

ATTORNEYS FOR PLAINTIFFS CANDELA CORPORATION and THE GENERAL HOSPITAL CORPORATION

Certificate of Service

I, hereby certify that a copy of the foregoing document was electronically filed in compliance with Local Rule CV-5(a). As such, this notice was served on all counsel who are deemed to have consented to electronic service on July 13, 2007.

/s/ Sam Baxter
Sam Baxter

EXHIBIT A

US005810801A

United States Patent [19]

Anderson et al.

[11] Patent Number: 5,810,801

[45] Date of Patent: Sep. 22, 1998

[54] **METHOD AND APPARATUS FOR TREATING WRINKLES IN SKIN USING RADIATION**

[75] Inventors: **R. Rox Anderson**, Lexington, Mass.; **Edward Victor Ross, Jr.**, San Diego, Calif.; **James C. Hsia**, Weston; **Kathleen McMillan**, Concord, both of Mass.

[73] Assignees: **Candela Corporation**, Wayland, Mass.; **The United States of America as represented by the Secretary of the Navy**, Washington, D.C.

[21] Appl. No.: **794,876**

[22] Filed: **Feb. 5, 1997**

[51] **Int. Cl.**[6] **A61B 17/36**

[52] **U.S. Cl.** **606/9**; 606/2; 606/23

[58] **Field of Search** 606/9, 2, 1, 20, 606/23, 21

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,672,969	6/1987	Dew	128/397
4,854,320	8/1989	Dew et al.	128/397
4,976,709	12/1990	Sand	606/5
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5,348,551	9/1994	Spears et al.	606/5
5,374,265	12/1994	Sand	606/5
5,409,479	4/1995	Dew et al.	606/9
5,437,658	8/1995	Muller et al.	606/5
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5,464,436	11/1995	Smith	606/9
5,484,432	1/1996	Sand	606/5

FOREIGN PATENT DOCUMENTS

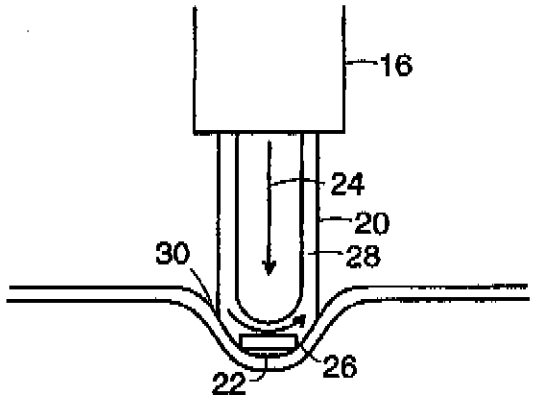
WO 95/15134 6/1995 WIPO .

Primary Examiner—Michael Powell Buiz
Assistant Examiner—Julian W. Woo
Attorney, Agent, or Firm—Testa, Hurwitz & Thibeault, LLP

[57] **ABSTRACT**

A method for treating wrinkles in skin involves the use of a beam of pulsed, scanned or gated continuous wave laser or incoherent radiation. The method comprises generating a beam of radiation, directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin, and thermally injuring collagen in the targeted dermal region. The beam of radiation has a wavelength of between 1.3 and 1.8 microns. The method may include cooling an area of the skin above the targeted dermal region while partially denaturing the collagen in the targeted dermal region. The method may also include cooling an area of the skin above the targeted dermal region prior to thermally injuring collagen in the targeted dermal region.

15 Claims, 2 Drawing Sheets



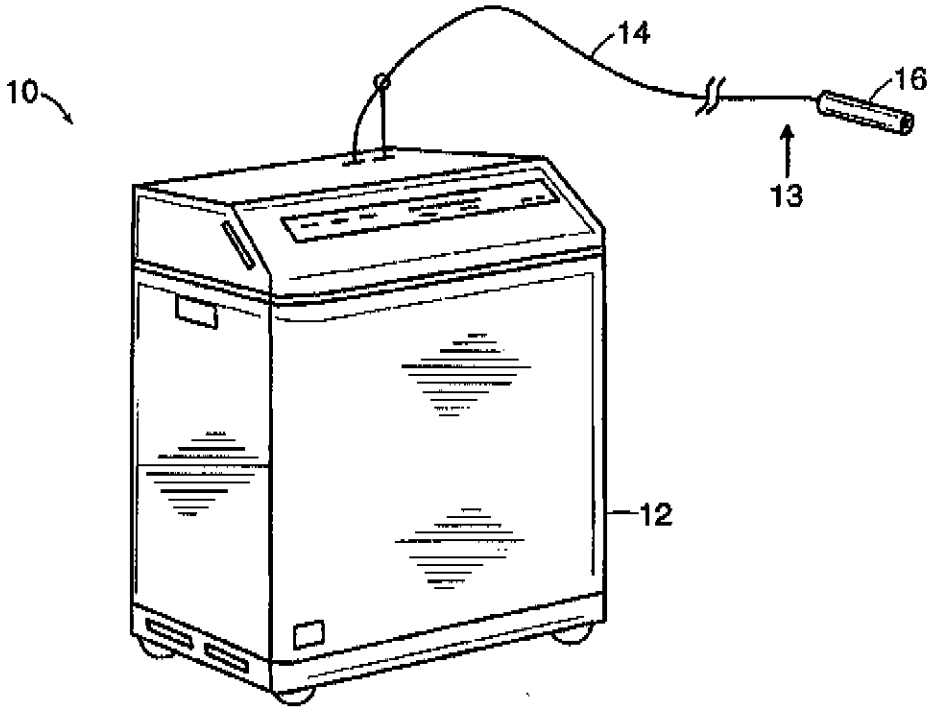


FIG. 1

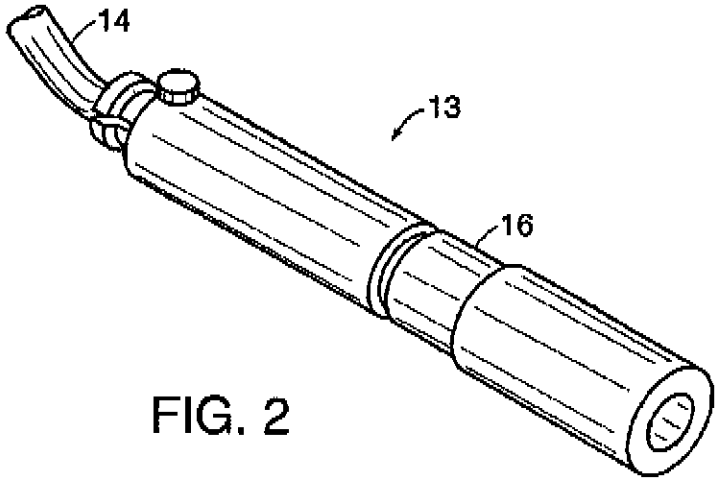


FIG. 2

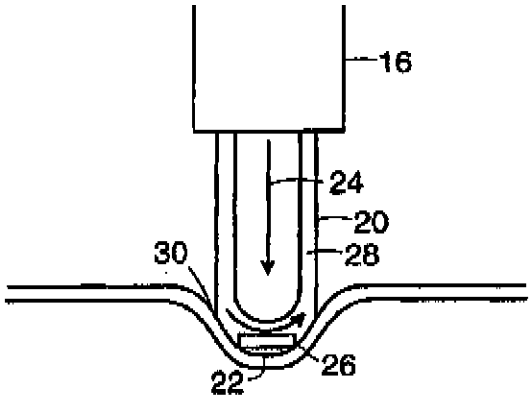


FIG. 3

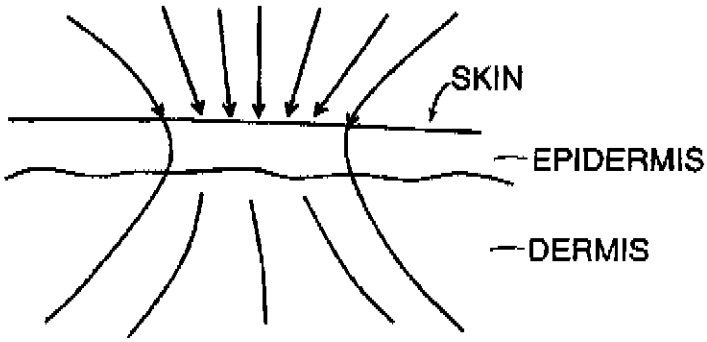


FIG. 4

METHOD AND APPARATUS FOR TREATING WRINKLES IN SKIN USING RADIATION

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

This invention was made with Government support under Grant Number N00014-94-1-0927 awarded by the Department of the Navy. The U.S. Government has certain rights in this invention.

FIELD OF THE INVENTION

The invention relates generally to the treatment of wrinkles in human skin using radiation. In particular, the invention relates to a method for treating wrinkles in human skin using a beam of laser or incoherent radiation to cause thermal injury in the dermal region of the skin sufficient to elicit a healing response that produces substantially unwrinkled skin.

BACKGROUND OF THE INVENTION

Undesired wrinkles in skin are commonly seen in dermatologic practice. Wrinkles in skin may be caused by age and by exposure to the sun's ultraviolet rays. Human skin consists mainly of two layers: the top layer of skin known as the epidermis; and the layer beneath the epidermis known as the dermis. The dermis is primarily acellular and is composed of water, the protein collagen, and glycosaminoglycans. Water constitutes approximately 70 percent of the total weight of the dermis. Collagen constitutes approximately 70 percent of the dry weight of the dermis, and glycosaminoglycans constitute between approximately 0.1 and 0.3 percent of the dry weight of the dermis. Collagen and glycosaminoglycans are constantly produced by fibroblasts, a type of connective tissue cell, and degraded by enzymes. Collagen degradation relies primarily on specific proteinases known as collagenases.

Collagen provides the dermis with the majority of its structural integrity. With aging, the amount of dermal collagen decreases and is replaced by the protein elastin. In addition, the remaining collagen tends to be chaotically oriented as compared to the more organized patterns found in youthful skin. Glycosaminoglycans are very hydrophilic, and increased amounts of these carbohydrates are associated with the increased skin vigor found in youthful skin. One major difference between the smooth, supple skin of newborns and the drier, thinned skin of older individuals is the far greater relative amount of glycosaminoglycans found in newborn skin. The glycosaminoglycans found in newborns can bind up to 1000 times their weight in water. As the skin ages and the amount of glycosaminoglycans decreases, the skin may become less hydrated and lose some of the suppleness found in youth. Also, the remaining glycosaminoglycans in photo-aged skin are deposited on the haphazardly arranged elastin fibers which have replaced the collagen fibers. The placement of the remaining glycosaminoglycans may partially account for the weather-beaten appearance of photo-aged skin.

Existing procedures for eliminating or reducing the severity of wrinkles include chemical peels, mechanical abrasion and laser ablation. All of these methods remove the top layer of skin. A new top layer forms during healing. Cosmetic improvement is seen when the skin containing wrinkles is replaced by a new layer of horizontally oriented neocollagen in the superficial dermis. However, all of these methods disrupt and completely remove the epidermis. The resulting

open wounds require daily care to optimize wound healing. Epidermal destruction and subsequent healing has several undesirable side effects. These undesirable side effects include prolonged hypopigmentation, hyperpigmentation, erythema and edema. Hyperpigmentation occurs frequently in darker skin types as a result of an inflammatory response of the skin. Hyperpigmentation results in the treated area of the subject's skin turning darker than the surrounding untreated skin. Hyperpigmentation can be slow to clear, sometimes taking up to a year to disappear. Hypopigmentation is attributable to damage to the melanin-producing cells in the skin. While generally transient, hypopigmentation can be permanent, and is cosmetically undesirable while it persists. Also, erythema or redness of the skin may be significant for weeks to months after the procedure, requiring the patients to wear conspicuous amounts of make-up.

A known property of collagen fibers, such as those found in the skin, is that the fibers shrink when elevated to a temperature in the range of 60 to 70 degrees Celsius, which is about 30 degrees Celsius above normal body temperature. Temperature elevation ruptures the collagen ultrastructural stabilizing cross-links, and results in immediate contraction in the collagen fibers to about one-third of their original length without changing the structural integrity of the fibers. One known technique shrinks the collagen fibers in the cornea of the eye to change the shape of the cornea and correct refractive disorders. This technique involves the use of laser energy in a wavelength range of about 1.80 to about 2.55 microns. The laser energy is used to irradiate the collagen in the cornea to elevate the collagen to at least 23 degrees Celsius above normal body temperature and thereby achieve collagen shrinkage. U.S. Pat. Nos. 4,976,709, 5,137,530, 5,304,169, 5,374,265, and 5,484,432 to Sand disclose a technique and apparatus for controlled thermal shrinkage of collagen fibers in the cornea.

However, this technique cannot be effectively used to remove wrinkles in skin by shrinking dermal collagen. The bulk of the shrunken, thermally denatured, collagen fibers do not remain in the skin after treatment with this technique. Unlike the cornea, which is avascular, an aggressive healing response in the skin degrades the denatured collagen in the superficial dermis by collagenases, thereby rapidly eliminating the bulk of the shrunken collagen from the skin.

Additionally, in the 1.80 to 2.55 micron wavelength range, strong absorption of the laser energy by water present in the skin limits the penetration depth of the laser radiation to a small fraction of a millimeter. The depths of thermal injury which can be achieved in skin using the wavelengths in this range are therefore limited to the most superficial layer of the skin. Such superficial injury leads to an inflammatory healing response characterized by prolonged visible edema and erythema, as well as the possibility for long lasting pigmentary disturbances.

SUMMARY OF THE INVENTION

The present invention addresses the foregoing problems and provides a method for inducing remodeling of the skin's extracellular matrix by partially denaturing the dermal collagen deeper in the skin, below the surface, while avoiding injury to the epidermis and upper layers of the dermis. The invention offers numerous advantages over existing dermatologic procedures and devices. The surface of the skin remains intact, thereby avoiding the need for dressing wounds; pigmentary disturbances are minimized; and any inflammatory response to the injury is mild and less visually evident.

In general, the present invention features a method for treating wrinkles in skin, without removing a layer of skin, using a beam of pulsed, scanned or gated continuous wave (CW) laser or incoherent radiation. The method comprises generating a beam of radiation having a wavelength between 1.3 and 1.8 microns, directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin, and thermally injuring the targeted dermal region to elicit a healing response that produces substantially less wrinkles.

More specifically, causing selective thermal injury to the dermis activates fibroblasts which deposit increased amounts of extracellular matrix constituents (i.e., collagen and glycosaminoglycans). These increases in extracellular matrix constituents are responsible for dermal skin rejuvenation and the reduced appearance of wrinkles.

In one embodiment, the beam of radiation causes partial denaturation of the collagen in the targeted dermal region. The partial denaturation of the collagen accelerates the collagen synthesis process by the fibroblasts and the deposition of new glycosaminoglycans, leading to the elimination or a reduction in the severity of the wrinkle. The method may also include cooling the surface of the skin and epidermal tissue above the targeted dermal region while irradiating the skin. The method may also include cooling the surface of the skin prior to irradiating the skin.

In a detailed embodiment, the method also includes stretching the skin along the wrinkle before directing the beam of radiation to the targeted dermal region below the wrinkle. Stretching the skin causes thermal injury to the collagen fibers across the wrinkle, while not affecting the fibers along the wrinkle.

The invention also relates to an apparatus for treating wrinkles in skin. The apparatus includes a radiation source and a delivery system which includes a cooling system. The radiation source generates a beam of radiation having a wavelength between 1.3 and 1.8 microns. The delivery system directs the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin. The cooling system cools the epidermal tissue above the targeted dermal region to minimize injury to the surface of the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will become apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings. The drawings are not necessarily to scale, emphasis instead being placed on illustrating the principles of the present invention.

FIG. 1 is an illustration of an apparatus including a radiation source and a delivery system for practicing the invention.

FIG. 2 is an enlarged perspective view of a delivery system incorporating the principles of the invention.

FIG. 3 is an illustration of a wrinkle in skin exposed to a plurality of radiation pulses.

FIG. 4 is an illustration of a region of skin exposed to a highly convergent beam of radiation.

DETAILED DESCRIPTION OF THE INVENTION

The present invention contemplates a system and method for removing wrinkles which includes delivering a beam of laser or incoherent radiation to cause sufficient thermal injury in the dermal region of the skin to elicit a healing response to cause the skin to remodel itself, resulting in more youthful looking (i.e., substantially unwrinkled) skin. In particular, thermal injury may be in the form of partial denaturation of the collagen fibers in the targeted dermal region of skin. In one embodiment, the radiation beam has a set of parameter ranges carefully selected to partially denature collagen in the dermis while protecting the epidermis by surface cooling. As a result, a subject treated using the method of the invention is able to have the appearance of wrinkles lessened without damage to the epidermis.

FIG. 1 is an illustration of a system 10 for practicing the invention. The system 10 includes a radiation source 12 and a delivery system 13. A beam of radiation generated by the radiation source 12 is directed to a target region of a subject's skin including a wrinkle via the delivery system 13. In one embodiment, the radiation source 12 is a laser. The laser may generate a beam of pulsed, scanned or gated CW laser radiation. In another embodiment, the radiation source 12 generates incoherent radiation.

The beam of radiation is directed to a targeted dermal region of skin between 100 microns and 1.2 millimeters below the wrinkle. The parameter ranges for the beam have been specifically selected to cause thermal injury to the dermis while avoiding injury to the epidermis and upper layers of the dermis. In particular, the wavelength of the radiation beam has been chosen to maximize absorption in the targeted region of the dermis, and the fluence or power density, depending on the type of radiation, has been chosen to minimize erythema. The wavelength range chosen has a tissue absorption coefficient preferably in the range of about 1 to 20 cm^{-1}. Thus, the beam preferably has a wavelength of between about 1.3 and 1.8 microns in one embodiment. Within this wavelength range, radiation energy applied through the surface of the skin is deposited predominantly in the dermal region of the skin. In one embodiment, the radiation beam has a nominal wavelength of approximately 1.5 microns. Lasers which produce radiation having wavelengths in the range of between about 1.3 and 1.8 microns include the 1.33 micron Nd:YAG laser, the 1.44 micron Nd:YAG laser and the 1.54 micron Er:Glass laser. The radiation beam may be pulsed, scanned or gated continuous wave laser radiation. In embodiments having a laser as the radiation source 12, the laser radiation generated preferably has a fluence of between about 10 and 150 joules.

In another embodiment, the radiation used to thermally injure the dermis is incoherent radiation. In embodiments using incoherent radiation, the incoherent radiation generated by the radiation source 12 preferably has a power density of between about 5 and 100 watts per square centimeter.

FIG. 2 is an enlarged perspective view of a delivery system 13 incorporating the principles of the invention. The delivery system 13 includes a fiber 14 having a circular cross-section and a handpiece 16. A beam of radiation having a circular cross-section is delivered by the fiber 14 to the handpiece 16. An optical system within the handpiece 16 projects an output beam of radiation to a targeted region of the subject's skin. A user holding the handpiece 16 irradiates the targeted region of the subject's skin including the wrinkle with output pulses from the beam.

To minimize thermal injury to the epidermis and the upper layers of the dermis, in one embodiment, the delivery system 13 includes a cooling system for cooling the surface of the skin prior to and/or during application of the radiation. In

this embodiment, the delivery system **13** is multi-functional and is capable of delivering radiation and cooling the surface of the skin at the same time. FIG. **3** shows one embodiment of a delivery system **13** which includes a cooling system. The handpiece **16** includes a skin contacting portion **20** which is brought into contact with the region of skin **22** receiving the beam of radiation **24**. The skin contacting portion **20** cools the epidermal region of skin **22** receiving the beam of radiation. The skin contacting portion **20** includes a sapphire window **26** and a fluid passage **28** which contains a cooling fluid. The cooling fluid may be a fluorocarbon type cooling fluid. The cooling fluid circulates through the fluid passage **28** and past the sapphire window **26** which is in contact with the epidermal region of skin **22** receiving the beam of radiation **24**.

In another embodiment, the delivery system **13** and the cooling system are separate systems. The cooling system may comprise a container of a cold fluid. Cooling of the surface of the skin is accomplished by briefly spraying the skin with the cold fluid which extracts heat from the skin on contact. The fluid used can also be a non-toxic substance with high vapor pressure at normal body temperature, such as a freon. These fluids extract heat from the skin by the virtue of evaporative cooling.

FIG. **3** illustrates the treatment of a wrinkle **30** in accordance with the invention. Radiation pulses are produced using the radiation source **12**, which may be a pulsed, scanned or gated CW laser or incoherent radiation source. The radiation pulses are directed toward the region **22** of the subject's skin containing the wrinkle **30** by the delivery system **13**. The radiation pulses are preferably directed to a targeted dermal region between 100 microns and 1.2 millimeters below the surface of the skin. In a detailed embodiment, the radiation pulses are focused to a region centered at a depth of about 750 microns. The targeted dermal region including a portion of the wrinkle **30** is then irradiated with radiation pulses exiting from the handpiece **16** until collagen in that region is partially denatured. To accomplish this, the collagen at the selected depth in the targeted dermal region is preferably heated to a temperature in the range of about 50 to 70 degrees Celsius. Partially denaturing collagen in the dermis accelerates the collagen synthesis process by the fibroblasts. The thermal injury caused by the radiation is mild and is only sufficient to elicit a healing response and cause the fibroblasts to produce new collagen. Excessive denaturation of collagen in the dermis causes prolonged edema, erythema, and potentially scarring.

The skin contacting portion **20** preferably cools the area of the skin above the targeted dermal region to temperatures below approximately 50 to 70 degrees Celsius during application of the radiation, so as not to cause collateral thermal damage to the epidermis. The radiation beam, due to its wavelength, does not sufficiently penetrate into depths below the targeted dermal region to cause thermal damage deeper in the skin. In one detailed embodiment, the skin contacting portion **20** cools an area of the skin above the targeted dermal region before the radiation is applied. The relative timing of cooling the surface of the skin to applying radiation depends, in part, on the depth to which thermal injury is to be prevented. Longer periods of cooling prior to the application of radiation allow more time for heat to diffuse out of the skin and cause a thicker layer of skin to be cooled, as compared to the thickness of the layer cooled by a short period of cooling. This thicker layer of cooled tissue sustains less thermal injury when the radiation energy is subsequently applied. Continued cooling of the surface of the skin during the delivery of radiation energy extracts heat from the upper layers of the skin as heat is deposited by the radiation, thereby further protecting the upper layers from thermal injury.

The depth of thermal injury caused by the radiation depends primarily on the penetration depth of the radiation used. The penetration depth can be approximated by taking the reciprocal of the absorption coefficient of the skin at the wavelength of the radiation. The thickness of the tissue overlying the zone of injury which is spared from injury depends primarily on the cooling applied prior to and/or during the delivery of radiation energy. By suitably choosing the radiation wavelength, the timing of the surface cooling, the cooling temperature, the radiation fluence and/or the power density as described above, the depth, the thickness and the degree of thermal injury can be confined to a zone within the dermis. These parameters can be chosen to optimally induce the injury required to elicit remodeling within the dermis, while substantially or completely sparing injury to the overlying epidermis and upper layers of the dermis.

In another detailed embodiment, the region of skin including the wrinkle **30** is stretched along the wrinkle **30** before the beam of radiation is directed to the targeted dermal region below the wrinkle **30**. Stretching the skin along the wrinkle before irradiating the skin causes partial denaturation of the collagen fibers across the wrinkle, while not damaging the fibers along the wrinkle. Partially denaturing the fibers across the wrinkle tightens the skin sufficiently to cause the wrinkle to disappear.

Referring to FIG. **4**, in one embodiment, to counteract the effects of scattering, the radiation beam is made highly convergent on the surface of the skin.

EXPERIMENTAL RESULTS

The method of the present invention for treating wrinkles in skin using radiation was applied in a series of in vivo experiments performed on pigs. A pulsed erbium glass laser producing radiation having a wavelength of approximately 1.54 microns was used as the radiation source **12**. The laser energy was applied to the pig skin via the skin contacting portion **20** equipped with a cooled sapphire window **26** at the tip, as described above and shown in FIGS. **1–3**. The inner surface of the sapphire window **26** was cooled by circulating refrigerated coolant, chilled to approximately minus 25 degrees Celsius through the passage **28**. The coolant used was a halocarbon which is transparent to the 1.54 micron laser radiation. The laser beam at the outer surface of the sapphire window **26** was approximately 5 mm in diameter.

The tip of the skin contacting portion **20** was placed in contact with the skin to cool the skin prior to applying the laser radiation. After a set amount of time (hereinafter "the pre-cooling time"), laser energy was applied to the skin. Various combinations of pre-cooling times, laser pulse energies, laser pulse repetition frequencies, time intervals of laser energy delivery, and total number of laser pulses delivered were studied. It was found that by the appropriate choice of these parameters, varying degrees of thermal injury can be achieved at varying depths in the dermis while preserving the viability of the epidermis and upper dermis.

For example, using a pre-cooling time of 5 seconds, a laser energy in the range of between 0.2 and 0.8 joules per pulse at a pulse repetition frequency of **4** Hertz (corresponding to an average laser power in the range between 0.8 to 3.2 watts), and a total of 24 pulses, it was found that varying degrees of thermal injury could be induced in a zone centered at a depth in the range of

approximately 0.5 to 1.0 millimeters beneath the surface of the skin, while avoiding injury to the epidermis and upper dermis.

Histology performed on biopsy samples taken at sites treated with the above range of parameters revealed collagen denaturation extending from about 100 microns in the dermis to about 1 mm deep. The epidermis and upper layers of the dermis were preserved as confirmed with nitrotetrazolium blue, a viability stain. In the cases in which only partial collagen denaturation was shown on histology, clinically, the treated areas showed an intact epidermis with mild edema and erythema which resolved completely within two weeks. Histologically, the treated sites showed greatly increased fibroblast activity, new collagen secretion and degradation of denatured collagen. By four weeks post treatment, the treated sites returned to normal, both clinically and histologically.

EQUIVALENTS

While the invention has been particularly shown and described with reference to specific embodiments, it should be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns and a fluence of between 10 and 150 joules per square centimeter;

directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin; and

causing thermal injury within the targeted dermal region to elicit a healing response that produces substantially unwrinkled skin.

2. The method of claim 1 wherein the wavelength is about 1.5 microns.

3. The method of claim 1 further comprising the step of stretching the skin along the wrinkle before the step of directing the beam of radiation to the targeted dermal region.

4. The method of claim 1 further comprising the step of cooling an epidermal region of the skin above the targeted dermal region contemporaneously with the step of causing thermal injury within the targeted dermal region.

5. The method of claim 4 further comprising the step of pre-cooling the epidermal region of the skin above the targeted dermal region before the step of causing thermal injury within the targeted dermal region.

6. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns and a power density of between 5 and 100 watts per square centimeter;

directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin; and

causing thermal injury within the targeted dermal region to elicit a healing response that produces substantially unwrinkled skin.

7. The method of claim 6 wherein the wavelength is about 1.5 microns.

8. The method of claim 6 further comprising the step of stretching the skin along the wrinkle before the step of directing the beam of radiation to the targeted dermal region.

9. The method of claim 6 further comprising the step of cooling an epidermal region of the skin above the targeted dermal region contemporaneously with the step of causing thermal injury within the targeted dermal region.

10. The method of claim 9 further comprising the step of pre-cooling the epidermal region of the skin above the targeted dermal region before the step of causing thermal injury within the targeted dermal region.

11. An apparatus for treating a wrinkle in human skin, comprising:

a source generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns; and

a delivery system coupled to the source, wherein the delivery system is for directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin, wherein the beam of radiation causes thermal injury to the targeted dermal region sufficient to elicit a healing response that produces substantially unwrinkled skin, the delivery system further comprising:

a cooling system for contact cooling an epidermal region of the skin above the targeted dermal region, to thereby minimize injury to the epidermal region.

12. The apparatus of claim 11 wherein the delivery system further comprises a fiber coupled to the source, the fiber carrying the beam of radiation; and

wherein the cooling system further comprises a skin contacting portion having a first end in optical communication with the fiber and a second end, the skin contacting portion projecting the beam of radiation toward the targeted dermal region through the second end of the skin contacting portion.

13. The apparatus of claim 12 wherein the skin contacting portion further comprises a window located at the second end of the skin contacting portion, the window being in optical communication with the fiber; and

wherein the skin contacting portion has a fluid passage extending across at least a portion of the window, the fluid passage circulating a cooling fluid past the window.

14. An apparatus for treating a wrinkle in human skin, comprising:

a source generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns;

a delivery system coupled to the source, wherein the delivery system is for directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters, below a wrinkle in the skin, wherein the beam of radiation causes thermal injury to the targeted dermal region sufficient to elicit a healing response that produces substantially unwrinkled skin; and

a cooling system for cooling an epidermal region of the skin above the targeted dermal region, to thereby minimize injury to the epidermal region.

15. The apparatus of claim 14 wherein the cooling system comprises a container of cold fluid, wherein the cold fluid can be sprayed onto the skin to extract heat from the skin on contact.

* * * * *

EXHIBIT B

US006120497A

United States Patent [19]

Anderson et al.

[11] Patent Number: 6,120,497

[45] Date of Patent: Sep. 19, 2000

[54] **METHOD AND APPARATUS FOR TREATING WRINKLES IN SKIN USING RADIATION**

[75] Inventors: **R. Rox Anderson**, Lexington, Mass.; **Edward Victor Ross, Jr.**, San Diego, Calif.; **James C. Hsia**, Weston; **Kathleen McMillan**, Concord, both of Mass.

[73] Assignees: **Massachusetts General Hospital**, Boston; **Candela Corporation**, Wayland, both of Mass.; **United States of America**, Washington, D.C.

[21] Appl. No.: **09/153,052**

[22] Filed: **Sep. 15, 1998**

Related U.S. Application Data

[63] Continuation of application No. 08/794,876, Feb. 5, 1997, Pat. No. 5,810,801.

[51] **Int. Cl.**[7] **A61B 18/18**

[52] **U.S. Cl.** **606/9**; 606/2; 606/23

[58] **Field of Search** 606/2, 9, 23

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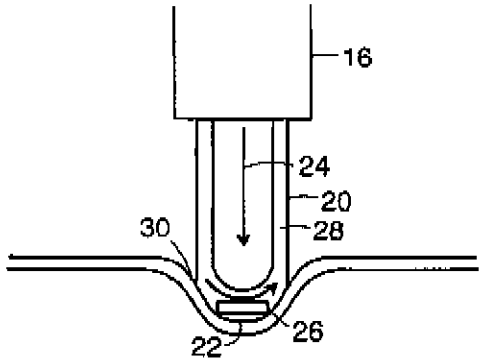
Primary Examiner—Michael Buiz
Assistant Examiner—Julian W. Woo
Attorney, Agent, or Firm—Testa, Hurwitz & Thibeault, LLP

[57] **ABSTRACT**

A method for treating wrinkles in skin involves the use of a beam of pulsed, scanned or gated continuous wave laser or incoherent radiation. The method comprises generating a beam of radiation, directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin, and thermally injuring collagen in the targeted dermal region. The beam of radiation has a wavelength of between 1.3 and 1.8 microns. The method may include cooling an area of the skin above the targeted dermal region while partially denaturing the collagen in the targeted dermal region. The method may also include cooling an area of the skin above the targeted dermal region prior to thermally injuring collagen in the targeted dermal region.

10 Claims, 2 Drawing Sheets



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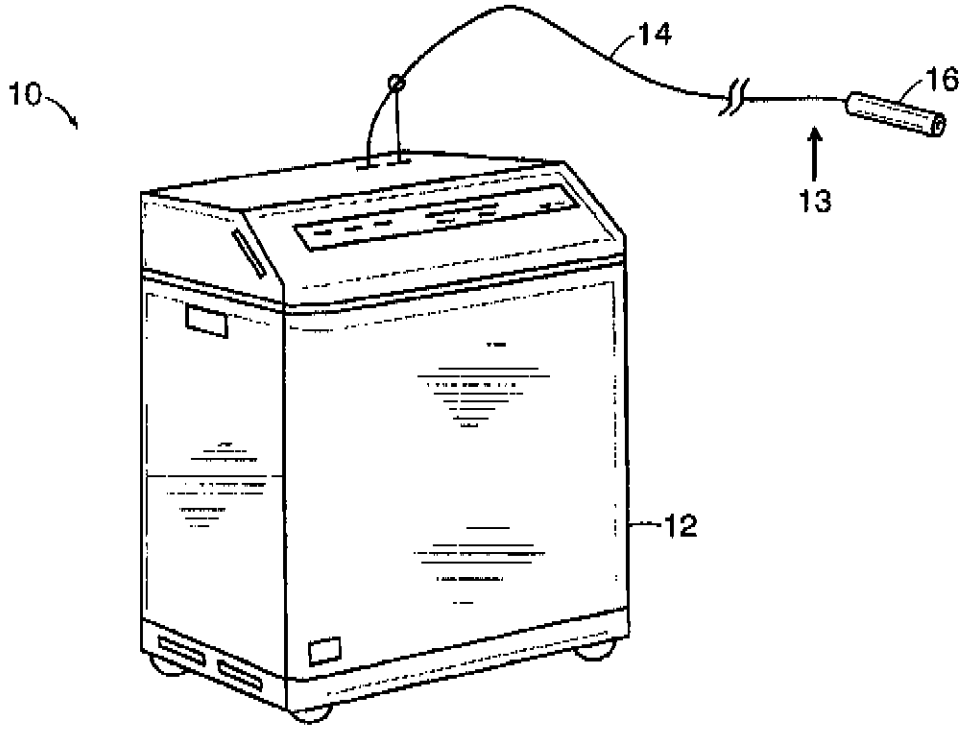

FIG. 1

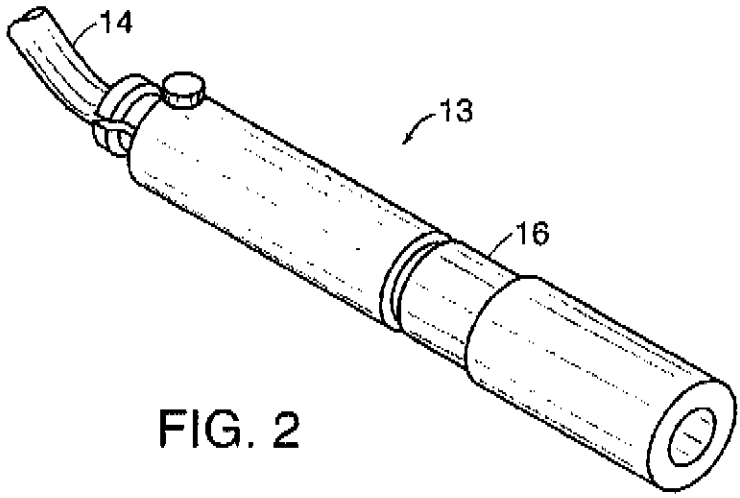

FIG. 2

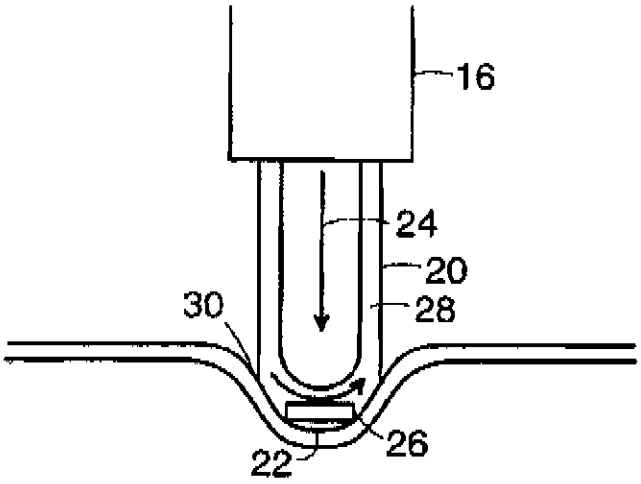

FIG. 3

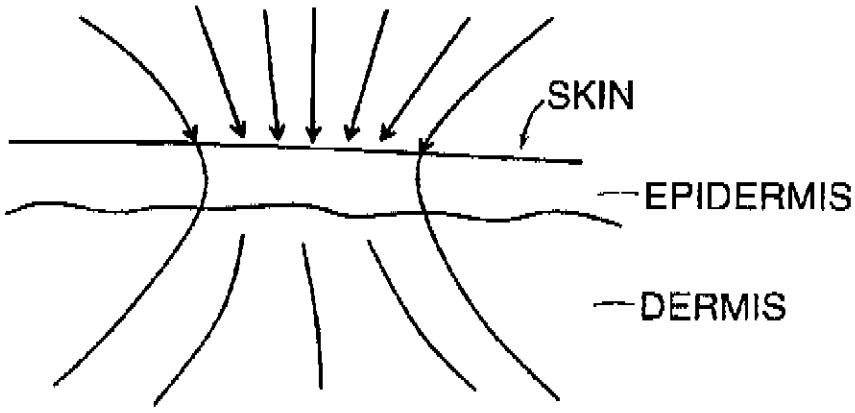

FIG. 4

METHOD AND APPARATUS FOR TREATING WRINKLES IN SKIN USING RADIATION

This application is a continuation of application Ser. No. 08/794,876, filed Feb. 5, 1997, now U.S. Pat. No. 5,810,801.

FIELD OF THE INVENTION

The invention relates generally to the treatment of wrinkles in human skin using radiation. In particular, the invention relates to a method for treating wrinkles in human skin using a beam of laser or incoherent radiation to cause thermal injury in the dermal region of the skin sufficient to elicit a healing response that produces substantially unwrinkled skin.

BACKGROUND OF THE INVENTION

Undesired wrinkles in skin are commonly seen in dermatologic practice. Wrinkles in skin may be caused by age and by exposure to the sun's ultraviolet rays. Human skin consists mainly of two layers: the top layer of skin known as the epidermis; and the layer beneath the epidermis known as the dermis. The dermis is primarily a cellular and is composed of water, the protein collagen, and glycosaminoglycans. Water constitutes approximately 70 percent of the total weight of the dermis. Collagen constitutes approximately 70 percent of the dry weight of the dermis, and glycosaminoglycans constitute between approximately 0.1 and 0.3 percent of the dry weight of the dermis. Collagen and glycosaminoglycans are constantly produced by fibroblasts, a type of connective tissue cell, and degraded by enzymes. Collagen degradation relies primarily on specific proteinases known as collagenases.

Collagen provides the dermis with the majority of its structural integrity. With aging, the amount of dermal collagen decreases and is replaced by the protein elastin. In addition, the remaining collagen tends to be chaotically oriented as compared to the more organized patterns found in youthful skin. Glycosaminoglycans are very hydrophilic, and increased amounts of these carbohydrates are associated with the increased skin vigor found in youthful skin. One major difference between the smooth, supple skin of newborns and the drier, thinned skin of older individuals is the far greater relative amount of glycosaminoglycans found in newborn skin. The glycosaminoglycans found in newborns can bind up to 1000 times their weight in water. As the skin ages and the amount of glycosaminoglycans decreases, the skin may become less hydrated and lose some of the suppleness found in youth. Also, the remaining glycosaminoglycans in photo-aged skin are deposited on the haphazardly arranged elastin fibers which have replaced the collagen fibers. The placement of the remaining glycosaminoglycans may partially account for the weather-beaten appearance of photo-aged skin.

Existing procedures for eliminating or reducing the severity of wrinkles include chemical peels, mechanical abrasion and laser ablation. All of these methods remove the top layer of skin. A new top layer forms during healing. Cosmetic improvement is seen when the skin containing wrinkles is replaced by a new layer of horizontally oriented neocollagen in the superficial dermis. However, all of these methods disrupt and completely remove the epidermis. The resulting open wounds require daily care to optimize wound healing. Epidermal destruction and subsequent healing has several undesirable side effects. These undesirable side effects include prolonged hypopigmentation, hyperpigmentation, erythema and edema. Hyperpigmentation occurs frequently

in darker skin types as a result of an inflammatory response of the skin. Hyperpigmentation results in the treated area of the subject's skin turning darker than the surrounding untreated skin. Hyperpigmentation can be slow to clear, sometimes taking up to a year to disappear. Hypopigmentation is attributable to damage to the melanin-producing cells in the skin. While generally transient, hypopigmentation can be permanent, and is cosmetically undesirable while it persists. Also, erythema or redness of the skin may be significant for weeks to months after the procedure, requiring the patients to wear conspicuous amounts of make-up.

A known property of collagen fibers, such as those found in the skin, is that the fibers shrink when elevated to a temperature in the range of 60 to 70 degrees Celsius, which is about 30 degrees Celsius above normal body temperature. Temperature elevation ruptures the collagen ultrastructural stabilizing cross-links, and results in immediate contraction in the collagen fibers to about one-third of their original length without changing the structural integrity of the fibers. One known technique shrinks the collagen fibers in the cornea of the eye to change the shape of the cornea and correct refractive disorders. This technique involves the use of laser energy in a wavelength range of about 1.80 to about 2.55 microns. The laser energy is used to irradiate the collagen in the cornea to elevate the collagen to at least 23 degrees Celsius above normal body temperature and thereby achieve collagen shrinkage. U.S. Pat. Nos. 4,976,709, 5,137,530, 5,304,169, 5,374,265, and 5,484,432 to Sand disclose a technique and apparatus for controlled thermal shrinkage of collagen fibers in the cornea.

However, this technique cannot be effectively used to remove wrinkles in skin by shrinking dermal collagen. The bulk of the shrunken, thermally denatured, collagen fibers do not remain in the skin after treatment with this technique. Unlike the cornea, which is avascular, an aggressive healing response in the skin degrades the denatured collagen in the superficial dermis by collagenases, thereby rapidly eliminating the bulk of the shrunken collagen from the skin.

Additionally, in the 1.80 to 2.55 micron wavelength range, strong absorption of the laser energy by water present in the skin limits the penetration depth of the laser radiation to a small fraction of a millimeter. The depths of thermal injury which can be achieved in skin using the wavelengths in this range are therefore limited to the most superficial layer of the skin. Such superficial injury leads to an inflammatory healing response characterized by prolonged visible edema and erythema, as well as the possibility for long lasting pigmentary disturbances.

SUMMARY OF THE INVENTION

The present invention addresses the foregoing problems and provides a method for inducing remodeling of the skin's extracellular matrix by partially denaturing the dermal collagen deeper in the skin, below the surface, while avoiding injury to the epidermis and upper layers of the dermis. The invention offers numerous advantages over existing dermatologic procedures and devices. The surface of the skin remains intact, thereby avoiding the need for dressing wounds; pigmentary disturbances are minimized; and any inflammatory response to the injury is mild and less visually evident.

In general, the present invention features a method for treating wrinkles in skin, without removing a layer of skin, using a beam of pulsed, scanned or gated continuous wave (CW) laser or incoherent radiation. The method comprises generating a beam of radiation having a wavelength between

1.3 and 1.8 microns, directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin, and thermally injuring the targeted dermal region to elicit a healing response that produces substantially less wrinkles.

More specifically, causing selective thermal injury to the dermis activates fibroblasts which deposit increased amounts of extracellular matrix constituents (i.e., collagen and glycosaminoglycans). These increases in extracellular matrix constituents are responsible for dermal skin rejuvenation and the reduced appearance of wrinkles.

In one embodiment, the beam of radiation causes partial denaturation of the collagen in the targeted dermal region. The partial denaturation of the collagen accelerates the collagen synthesis process by the fibroblasts and the deposition of new glycosaminogalycans, leading to the elimination or a reduction in the severity of the wrinkle. The method may also include cooling the surface of the skin and epidermal tissue above the targeted dermal region while irradiating the skin. The method may also include cooling the surface of the skin prior to irradiating the skin.

In a detailed embodiment, the method also includes stretching the skin along the wrinkle before directing the beam of radiation to the targeted dermal region below the wrinkle. Stretching the skin causes thermal injury to the collagen fibers across the wrinkle, while not affecting the fibers along the wrinkle.

The invention also relates to an apparatus for treating wrinkles in skin. The apparatus includes a radiation source and a delivery system which includes a cooling system. The radiation source generates a beam of radiation having a wavelength between 1.3 and 1.8 microns. The delivery system directs the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin. The cooling system cools the epidermal tissue above the targeted dermal region to minimize injury to the surface of the skin.

BRIEF OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will become apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings. The drawings are not necessarily to scale, emphasis instead being placed on illustrating the principles of the present invention.

FIG. 1 is an illustration of an apparatus including a radiation source and a delivery system for practicing the invention.

FIG. 2 is an enlarged perspective view of a delivery system incorporating the principles of the invention.

FIG. 3 is an illustration of a wrinkle in skin exposed to a plurality of radiation pulses.

FIG. 4 is an illustration of a region of skin exposed to a highly convergent beam of radiation.

DETAILED DESCRIPTION OF THE INVENTION

The present invention contemplates a system and method for removing wrinkles which includes delivering a beam of laser or incoherent radiation to cause sufficient thermal injury in the dermal region of the skin to elicit a healing response to cause the skin to remodel itself, resulting in more youthful looking (i.e., substantially unwrinkled) skin. In particular, thermal injury may be in the form of partial denaturation of the collagen fibers in the targeted dermal region of skin. In one embodiment, the radiation beam has a set of parameter ranges carefully selected to partially denature collagen in the dermis while protecting the epidermis by surface cooling. As a result, a subject treated using the method of the invention is able to have the appearance of wrinkles lessened without damage to the epidermis.

FIG. 1 is an illustration of a system 10 for practicing the invention. The system 10 includes a radiation source 12 and a delivery system 13. A beam of radiation generated by the radiation source 12 is directed to a target region of a subject's skin including a wrinkle via the delivery system 13. In one embodiment, the radiation source 12 is a laser. The laser may generate a beam of pulsed, scanned or gated CW laser radiation. In another embodiment, the radiation source 12 generates incoherent radiation.

The beam of radiation is directed to a targeted dermal region of skin between 100 microns and 1.2 millimeters below the wrinkle. The parameter ranges for the beam have been specifically selected to cause thermal injury to the dermis while avoiding injury to the epidermis and upper layers of the dermis. In particular, the wavelength of the radiation beam has been chosen to maximize absorption in the targeted region of the dermis, and the fluence or power density, depending on the type of radiation, has been chosen to minimize erythema. The wavelength range chosen has a tissue absorption coefficient preferably in the range of about 1 to 20 cm^{-1}. Thus, the beam preferably has a wavelength of between about 1.3 and 1.8 microns in one embodiment. Within this wavelength range, radiation energy applied through the surface of the skin is deposited predominantly in the dermal region of the skin. In one embodiment, the radiation beam has a nominal wavelength of approximately 1.5 microns. Lasers which produce radiation having wavelengths in the range of between about 1.3 and 1.8 microns include the 1.33 micron Nd:YAG laser, the 1.44 micron Nd:YAG laser and the 1.54 micron Er:Glass laser. The radiation beam may be pulsed, scanned or gated continuous wave laser radiation. In embodiments having a laser as the radiation source 12, the laser radiation generated preferably has a fluence of between about 10 and 150 joules.

In another embodiment, the radiation used to thermally injure the dermis is incoherent radiation. In embodiments using incoherent radiation, the incoherent radiation generated by the radiation source 12 preferably has a power density of between about 5 and 100 watts per square centimeter.

FIG. 2 is an enlarged perspective view of a delivery system 13 incorporating the principles of the invention. The delivery system 13 includes a fiber 14 having a circular cross-section and a handpiece 16. A beam of radiation having a circular cross-section is delivered by the fiber 14 to the handpiece 16. An optical system within the handpiece 16 projects an output beam of radiation to a targeted region of the subject's skin. A user holding the handpiece 16 irradiates the targeted region of the subject's skin including the wrinkle with output pulses from the beam.

To minimize thermal injury to the epidermis and the upper layers of the dermis, in one embodiment, the delivery system 13 includes a cooling system for cooling the surface of the skin prior to and/or during application of the radiation. In this embodiment, the delivery system 13 is multi-functional and is capable of delivering radiation and cooling the surface of the skin at the same time. FIG. 3 shows one embodiment of a delivery system 13 which includes a cooling system. The handpiece 16 includes a skin contacting portion 20

which is brought into contact with the region of skin **22** receiving the beam of radiation **24**. The skin contacting portion **20** cools the epidermal region of skin **22** receiving the beam of radiation. The skin contacting portion **20** includes a sapphire window **26** and a fluid passage **28** which contains a cooling fluid. The cooling fluid may be a fluorocarbon type cooling fluid. The cooling fluid circulates through the fluid passage **28** and past the sapphire window **26** which is in contact with the epidermal region of skin **22** receiving the beam of radiation **24**.

In another embodiment, the delivery system **13** and the cooling system are separate systems. The cooling system may comprise a container of a cold fluid. Cooling of the surface of the skin is accomplished by briefly spraying the skin with the cold fluid which extracts heat from the skin on contact. The fluid used can also be a non-toxic substance with high vapor pressure at normal body temperature, such as a freon. These fluids extract heat from the skin by the virtue of evaporative cooling.

FIG. **3** illustrates the treatment of a wrinkle **30** in accordance with the invention. Radiation pulses are produced using the radiation source **12**, which may be a pulsed, scanned or gated CW laser or incoherent radiation source. The radiation pulses are directed toward the region **22** of the subject's skin containing the wrinkle **30** by the delivery system **13**. The radiation pulses are preferably directed to a targeted dermal region between 100 microns and 1.2 millimeters below the surface of the skin. In a detailed embodiment, the radiation pulses are focused to a region centered at a depth of about 750 microns. The targeted dermal region including a portion of the wrinkle **30** is then irradiated with radiation pulses exiting from the handpiece **16** until collagen in that region is partially denatured. To accomplish this, the collagen at the selected depth in the targeted dermal region is preferably heated to a temperature in the range of about 50 to 70 degrees Celsius. Partially denaturing collagen in the dermis accelerates the collagen synthesis process by the fibroblasts. The thermal injury caused by the radiation is mild and is only sufficient to elicit a healing response and cause the fibroblasts to produce new collagen. Excessive denaturation of collagen in the dermis causes prolonged edema, erythema, and potentially scarring.

The skin contacting portion **20** preferably cools the area of the skin above the targeted dermal region to temperatures below approximately 50 to 70 degrees Celsius during application of the radiation, so as not to cause collateral thermal damage to the epidermis. The radiation beam, due to its wavelength, does not sufficiently penetrate into depths below the targeted dermal region to cause thermal damage deeper in the skin. In one detailed embodiment, the skin contacting portion **20** cools an area of the skin above the targeted dermal region before the radiation is applied. The relative timing of cooling the surface of the skin to applying radiation depends, in part, on the depth to which thermal injury is to be prevented. Longer periods of cooling prior to the application of radiation allow more time for heat to diffuse out of the skin and cause a thicker layer of skin to be cooled, as compared to the thickness of the layer cooled by a short period of cooling. This thicker layer of cooled tissue sustains less thermal injury when the radiation energy is subsequently applied. Continued cooling of the surface of the skin during the delivery of radiation energy extracts heat from the upper layers of the skin as heat is deposited by the radiation, thereby further protecting the upper layers from thermal injury.

The depth of thermal injury caused by the radiation depends primarily on the penetration depth of the radiation used. The penetration depth can be approximated by taking the reciprocal of the absorption coefficient of the skin at the wavelength of the radiation. The thickness of the tissue overlying the zone of injury which is spared from injury depends primarily on the cooling applied prior to and/or during the delivery of radiation energy. By suitably choosing the radiation wavelength, the timing of the surface cooling, the cooling temperature, the radiation fluence and/or the power density as described above, the depth, the thickness and the degree of thermal injury can be confined to a zone within the dermis. These parameters can be chosen to optimally induce the injury required to elicit remodeling within the dermis, while substantially or completely sparing injury to the overlying epidermis and upper layers of the dermis.

In another detailed embodiment, the region of skin including the wrinkle **30** is stretched along the wrinkle **30** before the beam of radiation is directed to the targeted dermal region below the wrinkle **30**. Stretching the skin along the wrinkle before irradiating the skin causes partial denaturation of the collagen fibers across the wrinkle, while not damaging the fibers along the wrinkle. Partially denaturing the fibers across the wrinkle tightens the skin sufficiently to cause the wrinkle to disappear.

Referring to FIG. **4**, in one embodiment, to counteract the effects of scattering, the radiation beam is made highly convergent on the surface of the skin.

Experimental Results

The method of the present invention for treating wrinkles in skin using radiation was applied in a series of in vivo experiments performed on pigs. A pulsed erbium glass laser producing radiation having a wavelength of approximately 1.54 microns was used as the radiation source **12**. The laser energy was applied to the pig skin via the skin contacting portion **20** equipped with a cooled sapphire window **26** at the tip, as described above and shown in FIGS. **1–3**. The inner surface of the sapphire window **26** was cooled by circulating refrigerated coolant, chilled to approximately minus 25 degrees Celsius through the passage **28**. The coolant used was a balocarbon which is transparent to the 1.54 micron laser radiation. The laser beam at the outer surface of the sapphire window **26** was approximately 5 mm in diameter.

The tip of the skin contacting portion **20** was placed in contact with the skin to cool the skin prior to applying the laser radiation. After a set amount of time (hereinafter "the pre-cooling time"), laser energy was applied to the skin. Various combinations of pre-cooling times, laser pulse energies, laser pulse repetition frequencies, time intervals of laser energy delivery, and total number of laser pulses delivered were studied. It was found that by the appropriate choice of these parameters, varying degrees of thermal injury can be achieved at varying depths in the dermis while preserving the viability of the epidermis and upper dermis.

For example, using a pre-cooling time of 5 seconds, a laser energy in the range of between 0.2 and 0.8 joules per pulse at a pulse repetition frequency of 4 Hertz (corresponding to an average laser power in the range between 0.8 to 3.2 watts), and a total of 24 pulses, it was found that varying degrees of thermal injury could be induced in a zone centered at a depth in the range of approximately 0.5 to 1.0 millimeters beneath the surface of the skin, while avoiding injury to the epidermis and upper dermis.

Histology performed on biopsy samples taken at sites treated with the above range of parameters revealed collagen denaturation extending from about 100 microns in the dermis to about 1 mm deep. The epidermis and upper layers

of the dermis were preserved as confirmed with nitrotetrazolium blue, a viability stain. In the cases in which only partial collagen denaturation was shown on histology, clinically, the treated areas showed an intact epidermis with mild edema and erythema which resolved completely within two weeks. Histologically, the treated sites showed greatly increased fibroblast activity, new collagen secretion and degradation of denatured collagen. By four weeks post treatment, the treated sites returned to normal, both clinically and histologically.

Equivalents

While the invention has been particularly shown and described with reference to specific embodiments, it should be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns and a fluence of between 10 and 150 joulesper square centimeter;

directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin;

cooling an epidermal region of the skin above the targeted dermal region; and

causing thermal injury within the targeted dermal region to elicit a healing response that produces substantially unwrinkled skin.

2. The method of claim 1 wherein the wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before the step of causing thermal injury within the targeted dermal region.

3. The method of claim 1 further comprising the step of stretching the skin adjacent the wrinkle before the step of directing the beam of radiation to the targeted dermal region.

4. The method of claim 1 wherein the cooling step comprises cooling an epidermal region of the skin above the targeted dermal region contemporaneously with the step of causing thermal injury within the targeted dermal region.

5. The method of claim 1 wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before and contemoraneously with the step of causing thermal injury within the targeted dermal region.

6. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength of between 1.3 and 1.8 microns and a power density of between 5 and 100 watts per square centimeter;

directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin;

cooling an epidermal region of the skin above the targeted dermal region; and

causing thermal injury within the targeted dermal region to elicit a healing response that produces substantially unwrinkled skin.

7. The method of claim 6 wherein the wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before the step of causing thermal injury within the targeted dermal region.

8. The method of claim 6 further comprising the step of stretching the skin adjacent the wrinkle before the step of directing the beam of radiation to the targeted dermal region.

9. The method of claim 6 wherein the cooling step comprises cooling an epidermal region of the skin above the targeted dermal region contemporaneously with the step of causing thermal injury within the targeted dermal region.

10. The method of claim 6 wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before and contemporaneously with the step of causing thermal injury within the targeted dermal region.

* * * * *

EXHIBIT C

US006659999B1

(12) **United States Patent**
Anderson et al.

(10) **Patent No.: US 6,659,999 B1**
(45) **Date of Patent: *Dec. 9, 2003**

(54) **METHOD AND APPARATUS FOR TREATING WRINKLES IN SKIN USING RADIATION**

(75) Inventors: **R. Rox Anderson**, Lexington, MA (US); **Edward Victor Ross, Jr.**, San Diego, CA (US); **James C. Hsia**, Weston, MA (US); **Kathleen McMillan**, Acton, MA (US)

(73) Assignee: **Candela Corporation**, Wayland, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 571 days.

This patent is subject to a terminal disclaimer.

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Related U.S. Application Data

(63) Continuation of application No. 09/153,052, filed on Sep. 15, 1998, now Pat. No. 6,120,497, which is a continuation of application No. 08/794,876, filed on Feb. 5, 1997, now Pat. No. 5,810,801.

(51) **Int. Cl.**[7] **A61B 18/18**

(52) **U.S. Cl.** **606/9**; 606/2; 606/23

(58) **Field of Search** 606/9, 2, 23

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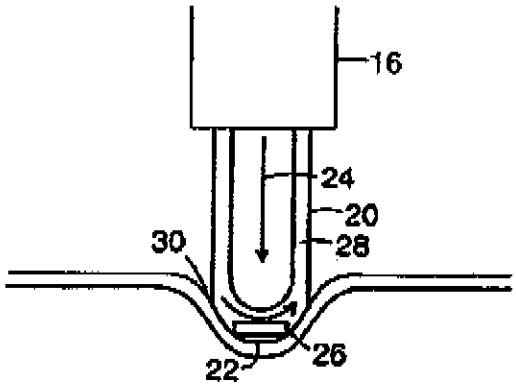
Primary Examiner—Julian W. Woo
(74) *Attorney, Agent, or Firm*—Testa, Hurwitz & Thibeault, LLP

(57) **ABSTRACT**

A method for treating wrinkles in skin involves the use of a beam of pulsed, scanned or gated continuous wave laser or incoherent radiation. The method comprises generating a beam of radiation, directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin, and thermally injuring collagen in the targeted dermal region. The beam of radiation has a wavelength of between 1.3 and 1.8 microns. The method may include cooling an area of the skin above the targeted dermal region while partially denaturing the collagen in the targeted dermal region. The method may also include cooling an area of the skin above the targeted dermal region prior to thermally injuring collagen in the targeted dermal region.

10 Claims, 2 Drawing Sheets



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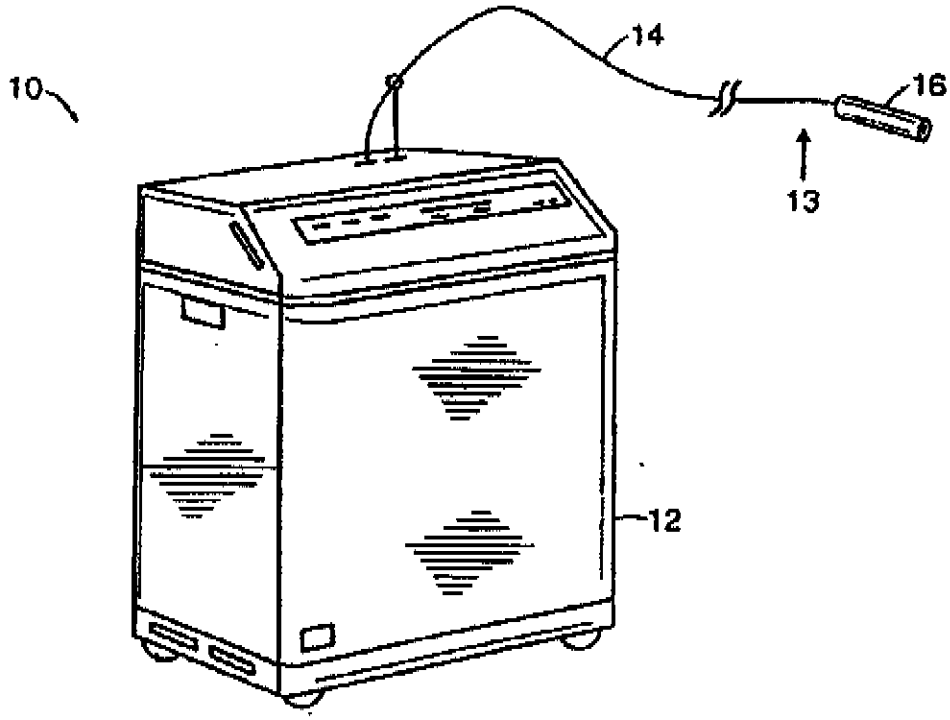

FIG. 1

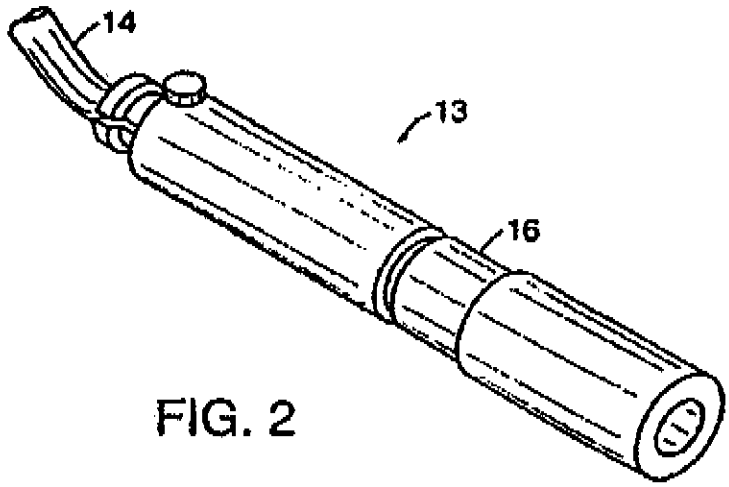

FIG. 2

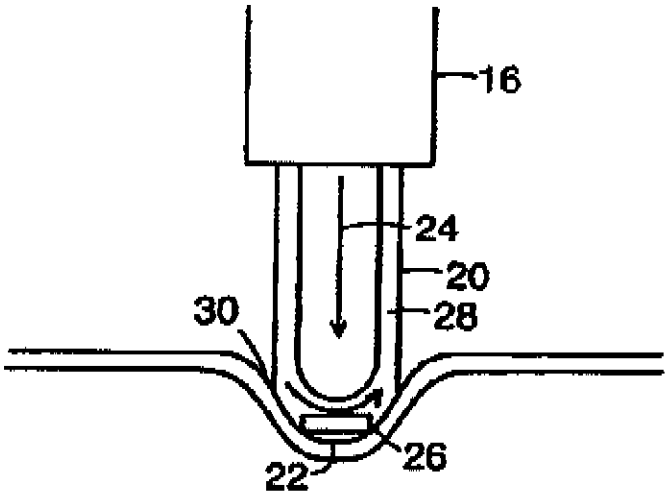

FIG. 3

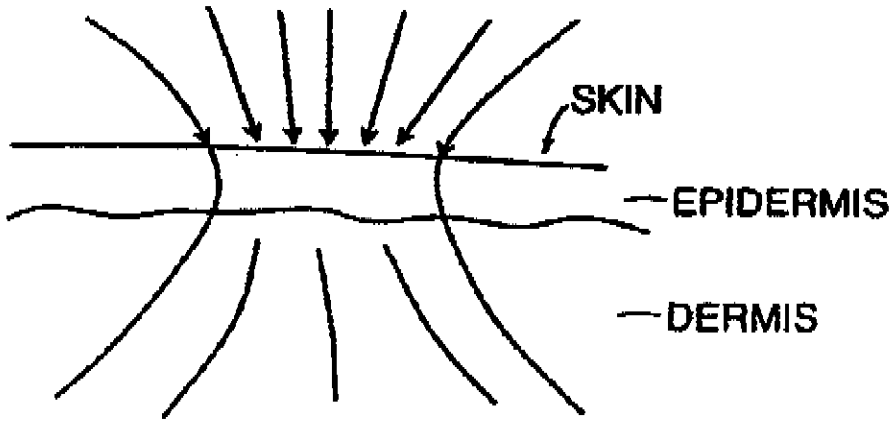

FIG. 4

METHOD AND APPARATUS FOR TREATING WRINKLES IN SKIN USING RADIATION

RELATED APPLICATION

This is a continuation of U.S. Ser. No. 09/153,052, filed Sep. 15, 1998, now U.S. Pat. No. 6,120,497 which is a continuation of U.S. Ser. No. 08/794,876, filed Feb. 5, 1997, which is now U.S. Pat. No. 5,810,801.

GOVERNMENT RIGHTS

This invention was made with Government support under Grant Number N00014-94-1-0927 awarded by the Department of the Navy. The U.S. Government has certain rights in this invention.

FIELD OF THE INVENTION

The invention relates generally to the treatment of wrinkles in human skin using radiation. In particular, the invention relates to a method for treating wrinkles in human skin using a beam of laser or incoherent radiation to cause thermal injury in the dermal region of the skin sufficient to elicit a healing response that produces substantially unwrinkled skin.

BACKGROUND OF THE INVENTION

Undesired wrinkles in skin are commonly seen in dermatologic practice. Wrinkles in skin may be caused by age and by exposure to the sun's ultraviolet rays. Human skin consists mainly of two layers: the top layer of skin known as the epidermis; and the layer beneath the epidermis known as the dermis. The dermis is primarily acellular and is composed of water, the protein collagen, and glycosaminoglycans. Water constitutes approximately 70 percent of the total weight of the dermis. Collagen constitutes approximately 70 percent of the dry weight of the dermis, and glycosaminoglycans constitute between approximately 0.1 and 0.3 percent of the dry weight of the dermis. Collagen and glycosaminoglycans are constantly produced by fibroblasts, a type of connective tissue cell, degraded by enzymes. Collagen degradation relies primarily on specific proteinases known as collagenases.

Collagen provides the dermis with the majority of its structural integrity. With aging, the amount of dermal collagen decreases and is replaced by the protein elastin. In addition, the remaining collagen tends to be chaotically oriented as compared to the more organized patterns found in youthful skin. Glycosaminoglycans are very hydrophilic, and increased amounts of these carbohydrates are associated with the increased skin vigor found in youthful skin. One major difference between the smooth, supple skin of newborns and the drier, thinned skin of older individuals is the far greater relative amount of glycosaminoglycans found in newborn skin. The glycosaminoglycans found in newborns can bind up to 1000 times their weight in water. As the skin ages and the amount of glycosaminoglycans decreases, the skin may become less hydrated and lose some of the suppleness found in youth. Also, the remaining glycosaminoglycans in photo-aged skin are deposited on the haphazardly arranged elastin fibers which have replaced the collagen fibers. The placement of the remaining glycosaminoglycans may partially account for the weather-beaten appearance of photo-aged skin.

Existing procedures for eliminating or reducing the severity of wrinkles include chemical peels, mechanical abrasion and laser ablation. All of these methods remove the top layer

of skin. A new top layer forms during healing. Cosmetic improvement is seen when the skin containing wrinkles is replaced by a new layer of horizontally oriented neocollagen in the superficial dermis. However, all of these methods disrupt and completely remove the epidermis. The resulting open wounds require daily care to optimize wound healing. Epidermal destruction and subsequent healing has several undesirable side effects. These undesirable side effects include prolonged hypopigmentation, hyperpigmentation, erythema and edema. Hyperpigmentation occurs frequently in darker skin types as a result of an inflammatory response of the skin. Hyperpigmentation results in the treated area of the subject's skin turning darker than the surrounding untreated skin. Hyperpigmentation can be slow to clear, sometimes taking up to a year to disappear. Hypopigmentation is attributable to damage to the melanin-producing cells in the skin. While generally transient, hypopigmentation can be permanent, and is cosmetically undesirable while it persists. Also, erythema or redness of the skin may be significant for weeks to months after the procedure, requiring the patients to wear conspicuous amounts of make-up.

A known property of collagen fibers, such as those found in the skin, is that the fibers shrink when elevated to a temperature in the range of 60 to 70 degrees Celsius, which is about 30 degrees Celsius above normal body temperature. Temperature elevation ruptures the collagen ultrastructural stabilizing cross-links, and results in immediate contraction in the collagen fibers to about one-third of their original length without changing the structural integrity of the fibers. One known technique shrinks the collagen fibers in the cornea of the eye to change the shape of the cornea and correct refractive disorders. This technique involves the use of laser energy in a wavelength range of about 1.80 to about 2.55 microns. The laser energy is used to irradiate the collagen in the cornea to elevate the collagen to at least 23 degrees Celsius above normal body temperature and thereby achieve collagen shrinkage. U.S. Pat. Nos. 4,976,709, 5,137,530, 5,304,169, 5,374,265, and 5,484,432 to Sand disclose a technique and apparatus for controlled thermal shrinkage of collagen fibers in the cornea.

However, this technique cannot be effectively used to remove wrinkles in skin by shrinking dermal collagen. The bulk of the shrunken, thermally denatured, collagen fibers do not remain in the skin after treatment with this technique. Unlike the cornea, which is avascular, an aggressive healing response in the skin degrades the denatured collagen in the superficial dermis by collagenases, thereby rapidly eliminating the bulk of the shrunken collagen from the skin.

Additionally, in the 1.80 to 2.55 micron wavelength range, strong absorption of the laser energy by water present in the skin limits the penetration depth of the laser radiation to a small fraction of a millimeter. The depths of thermal injury which can be achieved in skin using the wavelengths in this range are therefore limited to the most superficial layer of the skin. Such superficial injury leads to an inflammatory healing response characterized by prolonged visible edema and erythema, as well as the possibility for long lasting pigmentary disturbances.

SUMMARY OF THE INVENTION

The present invention addresses the foregoing problems and provides a method for inducing remodeling of the skin's extracellular matrix by partially denaturing the dermal collagen deeper in the skin, below the surface, while avoiding injury to the epidermis and upper layers of the dermis. The invention offers numerous advantages over existing derma-

tologic procedures and devices. The surface of the skin remains intact, thereby avoiding the need for dressing wounds; pigmentary disturbances are minimized; and any inflammatory response to the injury is mild and less visually evident.

In general, the present invention features a method for treating wrinkles in skin, without removing a layer of skin, using a beam of pulsed, scanned or gated continuous wave (CW) laser or incoherent radiation. The method comprises generating a beam of radiation having a wavelength between 1.3 and 1.8 microns, directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin, and thermally injuring the targeted dermal region to elicit a healing response that produces substantially less wrinkles.

More specifically, causing selective thermal injury to the dermis activates fibroblasts which deposit increased amounts of extracellular matrix constituents (i.e., collagen and glycosaminoglycans). These increases in extracellular matrix constituents are responsible for dermal skin rejuvenation and the reduced appearance of wrinkles.

In one embodiment, the beam of radiation causes partial denaturation of the collagen in the targeted dermal region. The partial denaturation of the collagen accelerates the collagen synthesis process by the fibroblasts and the deposition of new glycosaminoglycans, leading to the elimination or a reduction in the severity of the wrinkle. The method may also include cooling the surface of the skin and epidermal tissue above the targeted dermal region while irradiating the skin. The method may also include cooling the surface of the skin prior to irradiating the skin.

In a detailed embodiment, the method also includes stretching the skin along the wrinkle before directing the beam of radiation to the targeted dermal region below the wrinkle. Stretching the skin causes thermal injury to the collagen fibers across the wrinkle, while not affecting the fibers along the wrinkle.

The invention also relates to an apparatus for treating wrinkles in skin. The apparatus includes a radiation source and a delivery system which includes a cooling system. The radiation source generates a beam of radiation having a wavelength between 1.3 and 1.8 microns. The delivery system directs the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin. The cooling system cools the epidermal tissue above the targeted dermal region to minimize injury to the surface of the skin.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, features and advantages of the invention will become apparent from the following more particular description of preferred embodiments of the invention, as illustrated in the accompanying drawings. The drawings are not necessarily to scale, emphasis instead being placed on illustrating the principles of the present invention.

FIG. 1 is an illustration of an apparatus including a radiation source and a delivery system for practicing the invention.

FIG. 2 is an enlarged perspective view of a delivery system incorporating the principles of the invention.

FIG. 3 is an illustration of a wrinkle in skin exposed to a plurality of radiation pulses.

FIG. 4 is an illustration of a region of skin exposed to a highly convergent beam of radiation.

DETAILED DESCRIPTION OF THE INVENTION

The present invention contemplates a system and method for removing wrinkles which includes delivering a beam of laser or incoherent radiation to cause sufficient thermal injury in the dermal region of the skin to elicit a healing response to cause the skin to remodel itself, resulting in more youthful looking (i.e., substantially unwrinkled) skin. In particular, thermal injury may be in the form of partial denaturation of the collagen fibers in the targeted dermal region of skin. In one embodiment, the radiation beam has a set of parameter ranges carefully selected to partially denature collagen in the dermis while protecting the epidermis by surface cooling. As a result, a subject treated using the method of the invention is able to have the appearance of wrinkles lessened without damage to the epidermis.

FIG. 1 is an illustration of a system 10 for practicing the invention. The system 10 includes a radiation source 12 and a delivery system 13. A beam of radiation generated by the radiation source 12 is directed to a target region of a subject's skin including a wrinkle via the delivery system 13. In one embodiment, the radiation source 12 is a laser. The laser may generate a beam of pulsed, scanned or gated CW laser radiation. In another embodiment, the radiation source 12 generates incoherent radiation.

The beam of radiation is directed to a targeted dermal region of skin between 100 microns and 1.2 millimeters below the wrinkle. The parameter ranges for the beam have been specifically selected to cause thermal injury to the dermis while avoiding injury to the epidermis and upper layers of the dermis. In particular, the wavelength of the radiation beam has been chosen to maximize absorption in the targeted region of the dermis, and the fluence or power density, depending on the type of radiation, has been chosen to minimize erythema. The wavelength range chosen has a tissue absorption coefficient preferably in the range of about 1 to 20 cm^{-1}. Thus, the beam preferably has a wavelength of between about 1.3 and 1.8 microns in one embodiment. Within this wavelength range, radiation energy applied through the surface of the skin is deposited predominantly in the dermal region of the skin. In one embodiment, the radiation beam has a nominal wavelength of approximately 1.5 microns. Lasers which produce radiation having wavelengths in the range of between about 1.3 and 1.8 microns include the 1.33 micron Nd:YAG laser, the 1.44 micron Nd:YAG laser and the 1.54 micron Er:Glass laser. The radiation beam may be pulsed, scanned or gated continuous wave laser radiation. In embodiments having a laser as the radiation source 12, the laser radiation generated preferably has a fluence of between about 10 and 150 joules.

In another embodiment, the radiation used to thermally injure the dermis is incoherent radiation. In embodiments using incoherent radiation, the incoherent radiation generated by the radiation source 12 preferably has a power density of between about 5 and 100 watts per square centimeter.

FIG. 2 is an enlarged perspective view of a delivery system 13 incorporating the principles of the invention. The delivery system 13 includes a fiber 14 having a circular cross-section and a handpiece 16. A beam of radiation having a circular cross-section is delivered by the fiber 14 to the handpiece 16. An optical system within the handpiece 16 projects an output beam of radiation to a targeted region of the subject's skin. A user holding the handpiece 16 irradiates the targeted region of the subject's skin including the wrinkle with output pulses from the beam.

To minimize thermal injury to the epidermis and the upper layers of the dermis, in one embodiment, the delivery system **13** includes a cooling system for cooling the surface of the skin prior to and/or during application of the radiation. In this embodiment, the delivery system **13** is multi-functional and is capable of delivering radiation and cooling the surface of the skin at the same time. FIG. **3** shows one embodiment of a delivery system **13** which includes a cooling system. The handpiece **16** includes a skin contacting portion **20** which is brought into contact with the region of skin **22** receiving the beam of radiation **24**. The skin contacting portion **20** cools the epidermal region of skin **22** receiving the beam of radiation. The skin contacting portion **20** includes a sapphire window **26** and a fluid passage **28** which contains a cooling fluid. The cooling fluid may be a fluorocarbon type cooling fluid. The cooling fluid circulates through the fluid passage **28** and past the sapphire window **26** which is in contact with the epidermal region of skin **22** receiving the beam of radiation **24**.

In another embodiment, the delivery system **13** and the cooling system are separate systems. The cooling system may comprise a container of a cold fluid. Cooling of the surface of the skin is accomplished by briefly spraying the skin with the cold fluid which extracts heat from the skin on contact. The fluid used can also be a non-toxic substance with high vapor pressure at normal body temperature, such as a freon. These fluids extract heat from the skin by the virtue of evaporative cooling.

FIG. **3** illustrates the treatment of a wrinkle **30** in accordance with the invention. Radiation pulses are produced using the radiation source **12**, which may be a pulled, scanned or gated CW laser or incoherent radiation source. The radiation pulses are directed toward the region **22** of the subject's skin containing the wrinkle **30** by the delivery system **13**. The radiation pulses are preferably directed to a targeted dermal region between 100 microns and 1.2 millimeters below the surface of the skin. In a detailed embodiment, the radiation pulses are focused to a region centered at a depth of about 750 microns. The targeted dermal region including a portion of the wrinkle **30** is then irradiated with radiation pulses exiting from the handpiece **16** until collagen in that region is partially denatured. To accomplish this, the collagen at the selected depth in the targeted dermal region is preferably heated to a temperature in the range of about 50 to 70 degrees Celsius. Partially denaturing collagen in the dermis accelerates the collagen synthesis process by the fibroblasts. The thermal injury caused by the radiation is mild and is only sufficient to elicit a healing response and cause the fibroblasts to produce new collagen. Excessive denaturation of collagen in the dermis causes prolonged edema, erythema, and potentially scarring.

The skin contacting portion **20** preferably cools the area of the skin above the targeted dermal region to temperatures below approximately 50 to 70 degrees Celsius during application of the radiation, so as not to cause collateral thermal damage to the epidermis. The radiation beam, due to its wavelength, does not sufficiently penetrate into depths below the targeted dermal region to cause thermal damage deeper in the skin. In one detailed embodiment, the skin contacting portion **20** cools an area of the skin above the targeted dermal region before the radiation is applied. The relative timing of cooling the surface of the skin to applying radiation depends, in part, on the depth to which thermal injury is to be prevented. Longer periods of cooling prior to the application of radiation allow more time for heat to diffuse out of the skin and cause a thicker layer of skin to be cooled, as compared to the thickness of the layer cooled by a short period of cooling. This thicker layer of cooled tissue sustains less thermal injury when the radiation energy is subsequently applied. Continued cooling of the surface of the skin during the delivery of radiation energy extracts heat from the upper layers of the skin as heat is deposited by the radiation, thereby further protecting the upper layers from thermal injury.

The depth of thermal injury caused by the radiation depends primarily on the penetration depth of the radiation used. The penetration depth can be approximated by taking the reciprocal of the absorption coefficient of the skin at the wavelength of the radiation. The thickness of the tissue overlying the zone of injury which is spared from injury depends primarily on the cooling applied prior to and/or during the delivery of radiation energy. By suitably choosing the radiation wavelength, the timing of the surface cooling, the cooling temperature, the radiation fluence and/or the power density as described above, the depth, the thickness and the degree of thermal injury can be confined to a zone within the dermis. These parameters can be chosen to optimally induce the injury required to elicit remodeling within the dermis, while substantially or completely sparing injury to the overlying epidermis and upper layers of the dermis.

In another detailed embodiment, the region of skin including the wrinkle **30** is stretched along the wrinkle **30** before the beam of radiation is directed to the targeted dermal region below the wrinkle **30**. Stretching the skin along the wrinkle before irradiating the skin causes partial denaturation of the collagen fibers across the wrinkle, while not damaging the fibers along the wrinkle. Partially denaturing the fibers across the wrinkle tightens the skin sufficiently to cause the wrinkle to disappear.

Referring to FIG. **4**, in one embodiment, to counteract the effects of scattering, the radiation beam is made highly convergent on the surface of the skin.

Experimental Results

The method of the present invention for treating wrinkles in skin using radiation was applied in a series of in vivo experiments performed on pigs. A pulsed erbium glass laser producing radiation having a wavelength of approximately 1.54 microns was used as the radiation source **12**. The laser energy was applied to the pig skin via the skin contacting portion **20** equipped with a cooled sapphire window **26** at the tip, as described above and shown in FIGS. **1–3**. The inner surface of the sapphire window **26** was cooled by circulating refrigerated coolant, chilled to approximately minus 25 degrees Celsius through the passage **28**. The coolant used was a halocarbon which is transparent to the 1.54 micron laser radiation. The laser beam at the outer surface of the sapphire window **26** was approximately 5 mm in diameter.

The tip of the skin contacting portion **20** was placed in contact with the skin to cool the skin prior to applying the laser radiation. After a set amount of time (hereinafter "the pre-cooling time"), laser energy was applied to the skin. Various combinations of pre-cooling times, laser pulse energies, laser pulse repetition frequencies, time intervals of laser energy delivery, and total number of laser pulses delivered were studied. It was found that by the appropriate choice of these parameters, varying degrees of thermal injury can be achieved at varying depths in the dermis while preserving the viability of the epidermis and upper dermis.

For example, using a pre-cooling time of 5 seconds, a laser energy in the range of between 0.2 and 0.8 joules per pulse at a pulse repetition frequency of 4 Hertz

(corresponding to an average laser power in the range between 0.8 to 3.2 watts), and a total of 24 pulses, it was found that varying degrees of thermal injury could be induced in a zone centered at a depth in the range of approximately 0.5 to 1.0 millimeters beneath the surface of the skin, while avoiding injury to the epidermis and upper dermis.

Histology performed on biopsy samples taken at sites treated with the above range of parameters revealed collagen denaturation extending from about 100 microns in the dermis to about 1 mm deep. The epidermis and upper layers of the dermis were preserved as confirmed with nitrotetrazolium blue, a viability stain. In the cases in which only partial collagen denaturation was shown on histology, clinically, the treated areas showed an intact epidermis with mild edema and erythema which resolved completely within two weeks. Histologically, the treated sites showed greatly increased fibroblast activity, new collagen secretion and degradation of denatured collagen. By four weeks post treatment, the treated sites returned to normal, both clinically and histologically.

Equivalents

While the invention has been particularly shown and described with reference to specific embodiments, it should be understood by those skilled in the art that various changes in form and detail may be made therein without departing from the spirit and scope of the invention as defined by the appended claims.

What is claimed is:

1. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength within a range at which a tissue absorption coefficient is in the range of between 1 and 20 cm^{-1} and a fluence of between 10 and 150 joules per square centimeter;

directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin;

cooling an epidermal region of the skin above the targeted dermal region; and

causing thermal injury within the targeted dermal region to elicit a healing response that produces substantially unwrinkled skin.

2. The method of claim 1 wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before the step of causing thermal injury within the targeted dermal region.

3. The method of claim 1 further comprising the step of stretching the skin adjacent the wrinkle before the step of directing the beam of radiation to the targeted dermal region.

4. The method of claim 1 wherein the cooling step comprises cooling an epidermal region of the skin above the targeted dermal region contemporaneously with the step of causing thermal injury within the targeted dermal region.

5. The method of claim 1 wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before and contemporaneously with the step of causing thermal injury within the targeted dermal region.

6. A method for treating a wrinkle in human skin, comprising:

generating a beam of radiation having a wavelength within a range at which a tissue absorption coefficient is in the range of between 1 and 20 cm^{-1} and a power density of between 5 and 100 watts per square centimeter;

directing the beam of radiation to a targeted dermal region between 100 microns and 1.2 millimeters below a wrinkle in the skin;

cooling an epidermal region of the skin above the targeted dermal region: and

causing thermal injury within the targeted dermal region to elicit a healing response that produces substantially unwrinkled skin.

7. The method of claim 6 wherein the wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before the step of causing thermal injury within the targeted dermal region.

8. The method of claim 6 further comprising the step of stretching the skin adjacent the wrinkle before the step of directing the beam of radiation to the targeted dermal region.

9. The method of claim 6 wherein the cooling step comprises cooling an epidermal region of the skin above the targeted dermal region contemporaneously with the step of causing thermal injury within the targeted dermal region.

10. The method of claim 6 wherein the cooling step comprises cooling the epidermal region of the skin above the targeted dermal region before and contemporaneously with the step of causing thermal injury within the targeted dermal region.

* * * * *

Exhibit 2

OAO88 (Rev. 1/94) Subpoena in a Civil Case

Issued by the

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF ILLINOIS

CANDELA CORPORATION et al
v.
PALOMAR MEDICAL TECHNOLOGIES, INC.

SUBPOENA IN A CIVIL CASE

Case Number:[1] 9:06-CV-277-RHC
Eastern District of Texas

TO: Dr. Stanley Kovak
c/o John T. Gutkoski
Foley & Lardner LLP
111 Huntington Avenue
Boston, MA 02199-7610

YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at
X the place, date, and time specified below (list documents or objects): **See Schedule A.**

PLACE:	DATE:
Dr. Stanley Kovak 1200 S. York Rd. #4180 Elmhurst, IL 60126	**December 18, 2007**

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)	DATE:
Laura Handley McKool Smith P.C. 300 W. 6th Street Suite 1700 Austin, TX 78701 (512) 692-8700 Attorney for Plaintiffs	December 4, 2007

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on next page)

[1] If action is pending in district other than district of issuance, state district under case number.

PROOF OF SERVICE

DATE	PLACE

SERVED

SERVED ON (PRINT NAME)	MANNER OF SERVICE

SERVED BY (PRINT NAME)	TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____ _____
DATE SIGNATURE OF SERVER

_____
ADDRESS OF SERVER

RULE 45, FEDERAL RULES OF CIVIL PROCEDURE, PARTS C & D:

(c) **Protection of Persons Subject to Subpoenas.**(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee. (2)(A) A person commanded to produce and permit inspection, copying, testing, or sampling of designated electronically stored information, books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial. (B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection, copying, testing, or sampling may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to producing any or all of the designated materials or inspection of the premises -- or to producing electronically stored information in the form or forms requested. If objection is made, the party serving the subpoena shall not be entitled to inspect, copy, test, or sample the materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production, inspection, copying, testing, or sampling. Such an order to compel shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection, copying, testing, or sampling commanded. (3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it (i) fails to allow reasonable time for compliance; (ii) requires a person who is not a party or an officer of a party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(B)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held; (iii) requires disclosure of privileged or other protected matter and no exception or waiver applies; or (iv) subjects a person to undue burden. (B) If a subpoena (i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or (ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in

dispute and resulting from the expert's study made not at the request of any party, or (iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) **Duties in Responding to Subpoena**. (1)(A) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand. (B) If a subpoena does not specify the form or forms for producing electronically stored information, a person responding to a subpoena must produce the information in a form or forms in which the person ordinarily maintains it or in a form or forms that are reasonably usable. (C) A person responding to a subpoena need not produce the same electronically stored information in more than one form. (D) A person responding to a subpoena need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or to quash, the person from whom discovery is sought must show that the information sought is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery. (2)(A) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial-preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim. (B) If information is produced in response to a subpoena that is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has and may not use or disclose the information until the claim is resolved. A receiving party may promptly present the information to the court under seal for a determination of the claim. If the receiving party disclosed the information before being notified, it must take reasonable steps to retrieve it. The person who produced the information must preserve the information until the claim is resolved.

DEFINITIONS

1. The word "document" is used herein to include everything that is contemplated by Rule 34 of the Federal Rules of Civil Procedure, including, without limitation, any tangible thing and/or electronically stored information, any written, recorded, graphic, or printed matter, in whatever form, whether printed and/or produced or stored by hand, electronically, or any other process, including: (a) all originals, copies or drafts; and (b) originals, copies or drafts on which appear any notes or writings placed thereon after the document was first printed, typed, recorded, or made into graphic matter, however produced or reproduced, in the actual or constructive possession of the Recipient named in this subpoena.

2. The word "document" further includes, without limitation, letters; telegraphs; memoranda; writings; circulars; bulletins; manuals; speeches; audio and video tapes; photographs or other images, drawings; blueprints; recordings; computer disks, tapes or compilations; electronic or magnetic memory devices in readable form; computer printouts; computer electronic messages; electronic mail; websites or website materials; archives or backups; notes; correspondence; communications of any nature; summaries of records of conversations or conferences; information which can be retrieved by any process, test and/or analysis; laboratory notebooks; reports and data sheets; specifications; sketches; samples; devices; prototypes; minutes or reports and/or summaries of investigations; prior art searches and results thereof, including discussions or analyses thereof; opinions or reports of consultants; publications; articles; agreements and contracts; brochures; pamphlets; advertisements; letters to the trade; and any tangible things and/or electronically stored information within the scope of Fed R. Civ. P. 34(a)(l).

3. Attached to this Subpoena as Attachment 1 is a copy of the protective order that has been entered by the Court in this case to protect the confidentiality of documents produced during this Litigation. Patient information under the Health Insurance Portability and Access Act can be protected by designating the produced information as "confidential" or "highly confidential" pursuant to this protective order.

4. The phrasing of these requests for production shall be construed so as to make Recipient's responses inclusive rather than exclusive. Thus, the word "including" is intended to be comprehensive and means "including but not limited to." Similarly, the singular form of all words includes the plural form and the plural form of all words includes the singular form; the words "and" and "or" shall be interpreted as both conjunctive and disjunctive; the word "any" shall mean "any and all"; and the word "each" shall mean "each and every." Likewise, the use of the present tense includes the past tense and vice versa.

5. The term "communication" means the transmittal of information (in the form of facts, ideas, inquiries or otherwise).

6. The term "person" means any natural person or any business, legal or governmental entity or association.

7. The term "concerning" means relating to, referring to, discussing, describing, evincing, negating, constituting, summarizing, or analyzing.

8. The term "Palomar" as used herein means Palomar Medical Technologies, Inc., its officers, partners, members, employees, counsel, agents, consultants, predecessors, successors, assigns, directors, and representatives, and includes all United States and foreign affiliates, divisions, subsidiaries and joint ventures, and other legal entities that are wholly or partly owned or controlled by, and that wholly or partly own or control Palomar, either directly or indirectly, and the officers, employees, counsel, agents, consultants, and representatives of those affiliates, divisions, subsidiaries, joint ventures, and other legal entities.

9. The term "Candela" as used herein means Candela Corporation, its officers, partners, members, employees, counsel, agents, consultants, predecessors, successors, assigns, directors, and representatives, and includes all United States and foreign affiliates, divisions, subsidiaries and joint ventures, and other legal entities that are wholly or partly owned or controlled by, and that wholly or partly own or control Candela, either directly or indirectly, and the officers, employees, counsel, agents, consultants, and representatives of those affiliates, divisions, subsidiaries, joint ventures, and other legal entities.

10. The term "Electromagnetic Radiation" as used herein means any source of light energy, including without limitation lasers and incoherent radiation such as, by nonlimiting example, Intense Pulsed Light.

11. The term "Wrinkle Treatment" as used herein means application of Electromagnetic Radiation to skin for treatments that provide as a primary or peripheral benefit treating wrinkles, fine lines or rhytides/rhytids (including but not limited to the treatment of periorbital or perioral lines and deep corrections), correction of skin laxity, or performing skin smoothing, skin tightening, skin or facial rejuvenation, photorejuvination, photofacials, skin resurfacing, tissue coagulation or improvement of skin texture or tone.

12. The term "Relevant Product" as used herein means the Palomar handunits Lux IR, LuxDeep IR, Lux1540, Lux1540-Z, LuxB, LuxG, LuxY or Lux Ys (or any prototypes, improvements or new models or versions of any of the foregoing), in combination with any Palomar base unit, including, but not limited to, the StarLux 500, StarLux 300, EsteLux or MediLux, and all components thereof.

13. The term "Marketing/Seminar Materials" as used herein means any document concerning a Relevant Product for the performance of any Wrinkle Treatment that was provided to or published for the access of Customers or potential Customers, including, but not limited to, any product brochure, application brochure, before/after photograph or other image, press release, white paper, Palomar Webinar document, Palomar seminar document, trade show advertising, PowerPoint presentation, "Business Builders Kit" (as defined on Palomar's "Marketing Support" webpage), any document concerning the benefits provided by using a Relevant Product for Wrinkle Treatment, workshop materials, user group materials, direct mail, flyers, web page, web seminar, trade show advertising, booth messaging, or television, radio, or print media advertising or marketing, or documents concerning same (including, but not limited to, transcripts).

14. The term "Lux Club Materials" as used herein means any document that is or was accessible though the Lux Club portion of the Palomar website.

15. The term "Palomar Doctor" means any medical doctor who is known to Recipient to be employed by Palomar, known to Recipient to provide services such as training on behalf of Palomar, or known to Recipient to provide information to the public about any product or service sold or provided by Palomar.

16. The term "Treatment Plan" as used herein means any combination of parameters, including, but not limited to, one or more of fluency, spot size, pulse duration, or number of pulses, for use of a Relevant Product to perform a Wrinkle Treatment.

17. The term "Training Materials" as used herein means any document concerning any treatment for which a Relevant Product can be used or the manner of using a Relevant Product by anyone (including but not limited to Palomar, researchers, Palomar Doctors, Customers or potential Customers), including, but not limited to, any operations manuals (including revisions), any treatment fluence guide (including revisions), any quick reference guide (including revisions), any Treatment Plan, any clinical study protocol, any advanced treatment pearls, any clinical training materials (including all materials provided during or concerning an initial training session), any document provided by a clinical trainer, or any CD-ROM or any PowerPoint concerning how to use a Relevant Product.

18. The term "Sponsored Events" as used herein means any event paid for in whole or in part, advertised or promoted by, organized by or otherwise sponsored by Palomar that concerns the use of a Relevant Product for Wrinkle Treatment, including, but not limited to, any workshop, any demonstration, any hands-on event, any one-on-one session with a Palomar Doctor, or any user group event.

19. The phrase "Litigation" means the patent infringement case between Candela and Palomar relating to Candela's US Patent Nos. 5,810,801, 6,120,497 and 6,659,999 (Candela Corporation v. Palomar Medical Technologies Inc., Case No. 9-06-CV-277-RHC).

20. The term "Customer" means any person, medical practice or corporate entity that has purchased, leased or otherwise obtained access to use a Relevant Product.

21. The term "Patient" means any person who receives a consultation about a Wrinkle Treatment, is scheduled for a Wrinkle Treatment or receives at least one Wrinkle Treatment, including without limitation any such person who is actually or potentially receiving a Wrinkle Treatment free of charge, in exchange for products or services, or as part of a research or experimental procedure.

22. The term "Recipient" means the person named in this subpoena, in his or her personal as well as professional and/or business capacity, and includes without limitation those individuals in the employment or control of you, your medical practice or your business.

INSTRUCTIONS

1. The court has entered an Amended Protective Order (a copy of which is included herewith as Attachment 1) that protects the confidentiality of documents that Recipient produces in response to this subpoena.

2. Recipient must furnish all information and documents within his/her personal knowledge, possession, custody or control, as well as that which is reasonably available to him/her, including that in the possession of his/her attorneys, agents, employees, representatives and investigators, present or former. Produce color copies of (i) any photograph or other image of a person who has had a Wrinkle Treatment (including any photograph or image of such person before such Wrinkle Treatment) and (ii) any color graph, regardless of the analysis depicted thereby.

3. If Recipient asserts that information subject to this subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation material, the claim shall be made expressly and shall be supported by a description of the nature of the document, communication, or thing not produced that is sufficient to enable the demanding party to contest the claim. Fed. R. Civ. P. 45 (d)(2).

SCHEDULE A

Document Requests

1. All documents referring to this Litigation, drafted as a result of this Litigation, or provided to Palomar or some other person as a result of this Litigation.

2. All documents concerning Recipient's marketing of the Relevant Products for Wrinkle Treatments to actual or potential Patients, including without limitation copies of each draft or final version of Recipient's website and each brochure, pamphlet, flyer, mailer, CD-ROM, photograph or other image, PowerPoint presentation or article that was actually presented to or viewed by an actual or potential Patient, or available for presentation to or viewing by an actual or potential Patient, communications with any marketing consultant or firm regarding the same, or communications with Palomar regarding the same.

3. All documents concerning any communication between Recipient and either (i) Palomar, (ii) a Palomar Doctor, (iii) a Relevant Product owner who is known to Recipient, (iv) a Relevant Product potential purchaser who is known to Recipient, or (v) any person providing clinical training, where such communication is concerning the use, operation, sales, or marketing of a Relevant Product to perform a Wrinkle Treatment.

4. Documents showing the number of times Recipient, or any other person in Recipient's office or practice, has used the Relevant Product for any Wrinkle Treatment.

5. All documents concerning any evaluation of whether a Wrinkle Treatment with a Relevant Product has (i) reduced a wrinkle, fine line, rhytid, or rhytide in any way, (ii) improved skin tone or texture in any way, (iii) decreased laxity of the skin in any way; or (iv) achieved skin tightening in any way, including, but not limited to, measurements, evaluation of photographs or other images, statistical analyses, data summaries, any patient treatment form (including without limitation, patient progress reports, operative reports and progress or follow-up reports) or any feedback or self-evaluation from any Patient receiving a Wrinkle Treatment.

6. All before and after photographs or other images which were (i) provided to any of Palomar, a Palomar Doctor, a Patient or potential Patient, or a Customer or potential Customer; (ii) used by Recipient in any public presentation or publication; (iii) given by Recipient to any other person for use or potential use in any public presentation or publication; (iv) posted on the Lux Club website; or (v) used in any advertising materials by or on behalf of Recipient, wherein such photographs or images are depicting a person who has been treated with one or more of the Lux 1540, Lux 1540-Z, Lux IR, or Lux DeepIR for Wrinkle Treatment, and all communications with Palomar or with any person concerning any such photographs or other images, including, but not limited to, Patient consent forms.

7. All documents concerning any monetary or nonmonetary compensation (including without limitation complementary use of a laser, discounts, special pricing or stipends) Recipient has ever received from Palomar concerning the use of a Relevant Product for Wrinkle

Treatment, including, but not limited to, documents concerning the amount, the date, or the reason for the compensation.

8. All documents concerning the generation of any Wrinkle Treatment data for actual or potential submission to the FDA, including but not limited to, (i) all clinical study protocols for Wrinkle Treatment with a Relevant Product; (ii) all Wrinkle Treatments made pursuant to IDE G050009 or any other Investigative Device Exemption (IDE) for a Relevant Product (including without limitation all settings used on Relevant Products), (iii) all documents concerning any clinical study, clinical treatment or clinical data concerning the use of a Relevant Product for Wrinkle Treatment that is part of a study that is subject to review by an IRB or institutional ethics committee; (iv) all data and analyses (including raw data, photographs or other images, compilations, summaries or statistical analyses) generated pursuant to IDE G050009 or any other Investigative Device Exemption (IDE) for Wrinkle Treatment with a Relevant Product, (v) all documents concerning Palomar's intent or desire to get FDA clearance for use of a Relevant Product for any Wrinkle Treatment (or status or progress in gaining any such FDA clearance); and (vi) all documents concerning any draft or final 510(k) for the Lux IR, the Lux DeepIR, the Lux 1540 or the Lux 1540-z and concerning any aspect of Wrinkle Treatment.

9. All documents concerning feedback from Recipient's Patients regarding any Wrinkle Treatment using one or more of the Relevant Products, including, but not limited to, documents concerning any feedback regarding the results of such treatment or procedure.

10. All documents concerning Marketing/Seminar Materials, Lux Club Materials, Sponsored Events, Training Materials or Treatment Plans, including, but not limited to, who creates or pays for any of the foregoing Marketing/Seminar Materials, Lux Club Materials, Sponsored Events, Training Materials or Treatment Plans.

Attachment 1

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

CANDELA CORPORATION AND MASSACHUSETTS GENERAL HOSPITAL	§	
Plaintiffs,	§	
v.	§	**Civil Action No. 9-06-CV-277-RHC**
	§	**JURY TRIAL DEMANDED**
PALOMAR MEDICAL TECHNOLOGIES, INC.	§	
Defendant.	§	

AMENDED PROTECTIVE ORDER

The Court issues this Amended Protective Order to facilitate document disclosure and production under the Local Rules of this Court and the Federal Rules of Civil Procedure. Unless modified pursuant to the terms contained in this Order, this Order shall remain in effect through the conclusion of this litigation.

In support of this order, the court finds that:

1. All documents, materials, items, and/or information produced or submitted during the course of this action either by a party or by a nonparty to or for either of the parties shall be governed by this Protective Order.

2. Any information or materials produced by any party or nonparty as part of discovery in this action may be designated by such party or nonparty as "Confidential" or "Highly-Confidential" under the terms of this Protective Order.

3. Absent a specific order by this Court, once designated as "Confidential" or "Highly-Confidential" such designated information shall be used by the parties solely in

connection with this litigation, and not for any business, competitive, or governmental purpose or function, and such information shall not be disclosed to anyone except as provided herein.

4. Information or materials designated as "Confidential" are those things that the designating or producing party reasonably and in good faith believes contains or discloses confidential information that is non-public and that the designating or producing party would not ordinarily disclose to third parties, or if disclosed, would require such parties to maintain in confidence.

5. Information or materials designated as "Highly-Confidential" are those things that the designating or producing party reasonably and in good faith believes contains or discloses trade secrets or other particularly sensitive business or technical information, including active research and development activities for any product or device for which regulatory approval has not been sought.

6. The designation of information or material as "Confidential" or "Highly-Confidential" for purposes of this Protective Order shall be made in the following manner by the party or nonparty seeking protection:

(a) in the case of documents, exhibits, briefs, memoranda, interrogatory responses, responses to requests for admission, or other materials (apart from depositions or other pretrial or trial testimony): by affixing the legend "CONFIDENTIAL" or "HIGHLY-CONFIDENTIAL" (including suitable substitutes such as HIGHLY-CONFIDENTIAL - ATTORNEY'S EYES ONLY) to each page of any document containing any confidential information or material at the time such documents are produced or such information is disclosed, or as soon thereafter as the party or nonparty seeking protection becomes aware of the

confidential nature of the information or material disclosed and sought to be protected hereunder; and

(b) in the case of deposition testimony: (i) by a statement on the record, by counsel, during such deposition proceeding that the entire transcript or a portion thereof shall be designated as "Confidential" or "Highly-Confidential" hereunder; or (ii) by written notice of such designation sent by counsel to all parties within thirty (30) days of receipt of the transcript of the deposition. During a deposition, the deponent or his counsel, or any other counsel of record present at the deposition, may invoke the provisions of this Protective Order in a timely manner, giving adequate warning to counsel for the party or nonparty that testimony about to be given is deemed "Confidential" or "Highly-Confidential." The parties shall treat all deposition and other pretrial and trial testimony as "Highly-Confidential" hereunder until the expiration of thirty-one (31) days after the mailing (via overnight mail) to counsel of the transcript of the deposition. Unless so designated, any confidentiality is waived after the expiration of the 31-day period unless otherwise stipulated or ordered. The parties may modify this procedure for any particular deposition through agreement on the record at such deposition or proceeding or otherwise by written stipulation, without further order of the Court. If any document or information designated as "Confidential" or "Highly-Confidential" is used during the course of a deposition, that portion of the deposition record reflecting such confidential information shall be sealed and stamped with the designated degree of confidentiality, and access thereto shall be limited pursuant to the other terms of this Protective Order.

7. Information or material designated as "Confidential," or copies of extracts therefrom and compilations and summaries thereof, may be disclosed, summarized, described,

characterized, or otherwise communicated or made available in whole or in part only to the following persons:

(a) parties' outside counsel of record in this action and regular and temporary employees of such counsel to whom it is necessary that the information or material be shown for the purposes of this litigation;

(b) for each party, in-house counsel who represent that party with respect to this litigation, together with support staff reporting directly to such counsel, who are actively engaged in assisting outside counsel in the conduct of this litigation, with disclosure only to the extent necessary to perform such work. Disclosure to any individual designated under this category is conditioned upon compliance with Paragraph 11 herein;

(c) consultants as defined in Paragraph 9 herein and pursuant to the provisions of Paragraph 10 herein;

(d) the Court, pursuant to Paragraph 12 herein;

(e) court reporters and their necessary stenographic, videographic and clerical personnel employed in connection with this action;

(f) graphics or design services retained by counsel for a party for purposes of preparing demonstrative or other exhibits for deposition, trial or other court proceedings in this action, subject to and conditioned upon compliance with Paragraph 11 herein;

(g) non-technical jury or trial consulting services retained by counsel for a party, subject to and conditioned upon compliance with Paragraph 11 herein;

(h) the author, recipient or person with personal knowledge of such information or material; and

(i) any other person only upon order of the Court or upon written consent of the party producing the confidential information or material, subject to and conditioned upon compliance with Paragraph 11 herein.

8. Information or material designated as "Highly-Confidential," or copies or extracts therefrom and compilations and summaries thereof, may be disclosed, summarized, described, characterized, or otherwise communicated or made available in whole or in part only to persons listed in Paragraphs 7(a) and 7(c)-7(i), provided that if required by this Protective Order they first confirm their understanding and agreement to abide by the terms of this Protective Order by completing and signing a copy of an undertaking in the form attached hereto as Exhibit A.

9. For purposes of Paragraph 7(c) and 8 herein, a consultant shall be defined as a person who is neither an employee of a party nor anticipated to become an employee in the near future, and who is retained or employed as a bona fide consultant or expert for purposes of this litigation, whether full or part time, by or at the direction of counsel for a party.

10. The procedure for having a consultant approved for access to information or materials designated as "Confidential" or "Highly-Confidential" shall be as follows:

(a) The party seeking to have a consultant, as defined in Paragraph 9 herein, approved shall provide (via overnight delivery) the producing party with a current resume or curriculum vitae of such person, which shall include a description of past and present employers and persons or entities with whom the consultant has been engaged in any consulting relationships in the field of dermatologic or aesthetic lasers in the last ten years, and a copy of a completed and signed undertaking in the form attached hereto as Exhibit A.

(b) Unless the producing party objects in writing to the disclosure of confidential information to the designated person within ten (10) business days after the date on which the information described in Paragraph 10(a) was mailed, such consultant shall thereafter be deemed qualified to receive information designated "Confidential" or "Highly-Confidential." Any objection to a consultant must be in good faith and the reasons for the objection shall be stated in writing.

(c) If the producing party so objects, the parties shall, within fifteen (15) days from the date of mailing of notice of objection, confer and attempt to resolve the dispute. If the parties cannot resolve the dispute, or if the conference does not take place, then, within fifteen (15) days from the date of the conference and within thirty (30) days from the date of the mailing of notice of objection, the objecting party may move the Court for an order that access to information designated "Confidential" or "Highly-Confidential" be denied to the designated person. These time periods are not to restrict either party from moving for a court order earlier if the circumstances so require. Failure to file a motion within these periods shall constitute waiver of the specific objection, but shall not preclude a party from objection to continued access of confidential information where facts suggesting a basis for objection are subsequently learned by the party or its counsel.

11. All persons listed in Paragraphs 7(a) - 7(i) above may be given access to information or material designated as "Confidential," or "Highly Confidential" as permitted by Paragraph 8, provided that if required by this Protective Order they first confirm their understanding and agreement to abide by the terms of this Protective Order by completing and signing a copy of an undertaking in the form attached hereto as Exhibit A.

12. Pleadings, memoranda or other papers containing information or material designated as "Confidential" or "Highly-Confidential" as well as documents, interrogatory responses, responses to requests for admission, depositions transcripts, or other information or material designated as "Confidential" or "Highly-Confidential", where filed with the pleadings or as evidence, shall be filed under seal with the Clerk of the Court and shall not be available for public inspection. The title page of any document filed under seal which contains the information or material designated as "Confidential" or "Highly-Confidential" shall contain the style of the case, the title of pleading, and a statement substantially in the following form:

CONFIDENTIAL UNDER PROTECTIVE ORDER:

THIS DOCUMENT IS SUBJECT TO A PROTECTIVE ORDER ISSUED BY THE COURT. THIS DOCUMENT IS NOT TO BE SEEN NOR ARE THE CONTENTS TO BE EXAMINED, DISPLAYED, REVEALED, OR COPIED EXCEPT BY THE COURT, OR COURT PERSONNEL, OR IN COMPLIANCE WITH THE PROTECTIVE ORDER.

Courtesy copies of pleadings, memoranda or other papers containing information or material designated as "Confidential" or "Highly-Confidential" as well as documents, interrogatory responses, responses to requests for admission, depositions transcripts, or other information or material designated as "Confidential" or "Highly-Confidential" shall also be submitted in sealed envelopes with the case name and number of this action, the title of the paper which contains the information or material designated as "Confidential" or "Highly-Confidential" and a statement substantially in the following form:

CONFIDENTIAL UNDER PROTECTIVE ORDER:

THIS DOCUMENT IS SUBJECT TO A PROTECTIVE ORDER ISSUED BY THE COURT. THIS DOCUMENT IS NOT TO BE SEEN NOR ARE THE CONTENTS TO BE EXAMINED, DISPLAYED, REVEALED, OR COPIED EXCEPT BY THE COURT, OR COURT PERSONNEL, OR IN COMPLIANCE WITH THE PROTECTIVE ORDER.

13. A party may challenge the designation of information or materials produced herein as "Confidential" or "Highly-Confidential" by serving a written objection upon the producing party. The producing party shall notify the challenging party in writing of the bases for the asserted designation within ten (10) business days after receiving any written objection. The parties shall confer in good faith as to the validity of the designations within five (5) business days after the challenging party has received the notice of the bases for the asserted designation. To the extent the parties are unable to reach an agreement as to the designation, the objecting party may make an appropriate application to this Court within fifteen (15) days after conferring with the producing party, with confidential portions thereof to be kept under seal, requesting that specifically identified documents, information, and/or deposition testimony be excluded from the provisions of this Protective Order or downgraded in terms of the degree of protection provided. Failure to make an application within this period shall constitute a waiver of the objection. Until a dispute over the asserted designation is finally resolved by the parties or the Court, all parties and persons shall treat the information or materials in question as designated.

14. All "Confidential" or "Highly-Confidential" information and material covered by this Protective Order shall be kept in secure facilities, and access to those facilities shall be permitted only to those designated persons set forth in Paragraph 7 above as persons properly having access thereto.

15. All counsel for the parties who have access to information or material designated as "Confidential" or "Highly-Confidential" under this Protective Order acknowledge they are bound by this Order and submit to the jurisdiction of this Court for purposes of enforcing this Order.

16. Entering into, agreeing to, and/or producing or receiving information or material designated as "Confidential" or "Highly-Confidential" or otherwise complying with the terms of this Protective Order shall not:

(a) operate as an admission by any party that any particular information or material designated as "Confidential" or "Highly-Confidential" contains or reflects trade secrets, proprietary or commercially sensitive information, or any other type of confidential information;

(b) operate as an admission by any party that the restrictions and procedures set forth herein constitute or do not constitute adequate protection for any particular information deemed by any party to be "Confidential" or "Highly-Confidential";

(c) prejudice in any way the rights of the parties to object to the production of documents they consider not subject to discovery;

(d) prejudice in any way the rights of any party to object to the authenticity or admissibility into evidence of any document, testimony or other evidence subject to this Protective Order.

(e) prejudice in any way the rights of a party to seek a determination by the Court whether any information or material should be subject to the terms of this Protective Order;

(f) prejudice in any way the rights of a party to petition the Court for a further protective order relating to any purportedly confidential information; or

(g) prevent the parties to this Protective Order from agreeing in writing or on the record during a deposition in this action on alter or waive the provisions or protections provided for herein with respect to any particular information or material.

17. This Protective Order has no effect upon, and shall not apply to, a party's use or disclosure of its own confidential information for any purpose. Nothing contained herein shall impose any restrictions on the use or disclosure by a party of documents, information or material designated as "Confidential" or "Highly-Confidential" obtained lawfully by such party independently of any proceedings in this action, or which:

(a) was already known to such party by lawful means prior to acquisition from, or disclosure by, the other party in this action or a non-party;

(b) is or becomes publicly known through no fault or act of such party; or

(c) is rightfully received by such party from a third party that has authority to provide such information or material and without restriction as to disclosure.

18. In the event that information in the possession or control of a party involves the confidentiality rights of a non-party or its disclosure would violate a Protective Order issued in another action, the party with possession or control of the information will attempt to obtain the consent of the non-party to disclose the information under this Order. If the consent of the non-party cannot be obtained, the party will notify the party seeking discovery of: (a) the existence of the information without producing such information and; (b) the identity of the non-party (provided, however, that such disclosure of the identity of the non-party does not violate any confidentiality obligations). The party seeking discovery may then make further application to the non-party or seek other means to obtain such information.

19. If a party inadvertently produces "Confidential" or "Highly-Confidential" information without marking it as such, it may be disclosed to others until the receiving party becomes aware of the error, unless it appears from the face of the document that it contains non-

public, confidential, proprietary, commercially sensitive, or trade secret information of the producing party. As soon as the receiving party becomes aware of the inadvertent production, the information must be treated as if it had been timely designated under this Protective Order, and the receiving party must endeavor in good faith to obtain all copies of the document which it distributed or disclosed to persons not authorized to access such information by Paragraph 7 above, as well as any copies made by such persons.

20. If a party inadvertently produces a document that it later discovers to be a privileged document, the production of that document shall not be deemed to constitute the waiver of any applicable privileges. In such circumstances, the producing party must immediately notify the receiving party of the inadvertent production, and request the return or confirmed destruction of the privileged materials. Within five (5) business days of receiving such notification, the receiving party shall return or confirm destruction of all such materials, including any summaries thereof. Such return or confirmation of destruction shall not preclude the receiving party from seeking to compel production of the materials for reasons other than its inadvertent production.

21. The terms of this Protective Order shall apply to all manner and means of discovery, including entry onto land or premises, and inspection of books, records, documents, and tangible things.

22. It is the present intention of the parties that the provisions of this Protective Order shall govern discovery and other pretrial proceedings in this action. Nonetheless, each of the parties hereto shall be entitled to seek modification of this Protective Order by application to the Court on notice to the other party hereto for good cause.

23. The parties agree to be bound by the terms of this Protective Order pending its entry by the Court, or pending the entry of an alternative thereto which is satisfactory to all parties, and any violation of its terms shall be subject to the same sanctions and penalties as if the Protective Order had been entered by the Court.

24. The provisions of this Protective Order shall, absent written permission of the Producing Party or further order of the Court, continue to be binding throughout and after the conclusion of this action, including without limitation any appeals therefrom. Within sixty (60) days after receiving notice of the entry of an order, judgment or decree finally disposing of this action, including any appeals therefrom, all persons, except the court and court personnel, having received information or material designated as "Confidential" or "Highly-Confidential" hereunder shall return such material and all copies thereof (including summaries and excerpts) to counsel for the producing party, or shall certify destruction thereof. Counsel described in Paragraph 7(a) above shall be entitled to retain court papers, deposition and trial transcripts and attorney work product (including court papers,transcripts, and attorney work product that contain information or material designated as "Confidential" or "Highly-Confidential") provided that such counsel, and employees of such counsel, shall not disclose any such information and material designated as "Confidential" or "Highly-Confidential" contained in such court papers, transcripts, or attorney work product to any person or entity except pursuant to a written agreement with the producing party of the information or material.
All materials returned to the parties or their counsel by the Court
likewise shall be disposed of in accordance with this paragraph.

25. In the event that any information or material designated as "Confidential" or "Highly-Confidential" hereunder is used in any court proceeding in this action or any appeal therefrom, such information or material shall not lose its status as "Confidential" or "Highly-

Confidential" through such use. Counsel for the parties shall confer on such procedures as are necessary to protect the confidentiality of any documents, information and transcripts used in the course of any court proceedings, and shall incorporate such procedures, as appropriate, in the pre-trial order.

26. If any party (a) is subpoenaed in another action, (b) is served with a demand in another action to which it is a party, or (c) is served with any other legal process by one not a party to this action, seeking information or material which was produced or designated as "Confidential" or "Highly-Confidential" by someone other than that party, the party shall give prompt actual written notice, by hand or facsimile transmission, within ten (10) business days of receipt of such subpoena, demand or legal process, to those who produced or designated the information or material "Confidential" or "Highly-Confidential" and shall object to its production to the extent permitted by law. Should the person seeking access to the information or material take action against the party or anyone else covered by this Protective Order to enforce such a subpoena, demand or other legal process, the party shall respond by setting forth the existence of this Protective Order. Nothing herein shall be construed as requiring the party or anyone else covered by this Protective Order to challenge or appeal any order requiring production of information or material covered by this Protective Order, or to subject itself to any penalties for noncompliance with any legal process or order, or to seek any relief from this Court.

So **ORDERED** and **SIGNED** this **23** day of **May, 2007.**

Ron Clark, United States District Judge

EXHIBIT A

UNDERTAKING OF _____

I, _____, declare:

1. My address is _____

_____

_____

2. My present occupation is _____

3. I have received a copy of the Stipulated Protective Order in the action entitled *Candela Corporation, et al. v. Palomar Medical Technologies*, Case No. 9-06-CV-277. I have carefully read and understand the provisions of the Protective Order.

4. I will comply with all of the provisions of the Protective Order. I will hold in confidence, will not disclose to anyone other than those persons specifically authorized by the Protective Order, and will not copy or use except for purposes of the Action, any information designated "Confidential" or "Highly-Confidential" which I receive in the Action.

Executed this ____ day of _____, _____ at _____

_____ _____

I declare under penalty of perjury that the foregoing is true and correct.

_____

Exhibit 3

FOLEY
FOLEY & LARDNER LLP

ATTORNEYS AT LAW
111 HUNTINGTON AVENUE
BOSTON, MASSACHUSETTS 02199
617.342.4000 TEL
617.342.4001 FAX
www.foley.com

WRITER'S DIRECT LINE
617.342.4078
sriden@foley.com EMAIL

CLIENT/MATTER NUMBER
090577-0101

December 14, 2007

VIA E-MAIL AND U.S. MAIL

John Shumaker, Esquire
McKool Smith
300 West 6th Street, Suite 1700
Austin, TX 78701

RE: *Candela Corporation and Massachusetts General Hospital v. Palomar Medical Technologies, Inc.*, Civ. Action No. 9-06-CV-277-RHC

Dear John:

Please be advised that this firm represents Dr. Stanley Kovak. We are in receipt of a subpoena *duces tecum* to Dr. Kovak (the "Subpoena"), issued on behalf of Candela Corporation in the litigation referenced above. The Subpoena, dated December 6, 2007, purports to recite a return date of December 20, 2007.

Pursuant to Fed. R. Civ. P. 45(c), by this letter Dr. Kovak objects to the Subpoena on the following grounds:

GENERAL OBJECTIONS

Dr. Kovak incorporates each of the following General Objections in his specific responses to the Subpoena:

1. Dr. Kovak objects to the Subpoena as overly broad, impermissibly vague, and not reasonably limited in scope of time.

2. Dr. Kovak objects to the Subpoena as unduly burdensome and on the grounds that compliance with its terms will cause Dr. Kovak undue expense. In this regard, the Subpoena potentially encompasses thousands of patient files and may require hundreds of hours of physician and administrative time to identify responsive medical records among many thousands of other records. After responsive records are identified, extensive redaction of those records would be required. Such redaction would include not only information regarding patient identification, but also any unrelated personal information recorded in each file.

3. Dr. Kovak objects to the Subpoena on the grounds that – in light of the number of requests and the volume of documents requested – it provides an unreasonably

short time to respond, in that the Subpoena purports to direct compliance on December 20, 2007.

4. Dr. Kovak objects to the Subpoena to the extent that it seeks the production of documents protected by the attorney-client privilege, the work product privilege, or any other applicable privilege.

5. Dr. Kovak objects to the Subpoena to the extent that it seeks medical records and patient files because, *inter alia*, the current protective order in this lawsuit is insufficient, as it does not contain any reference to HIPAA and does not specifically address medical records or patient information. See 45 C.F.R. § 164.512 (e). In this vein, the Subpoena violates the "strong federal policy in favor of protecting the privacy of patient medical records." *Equal Employment Opportunity Comm'n v. Boston Market Corp.*, 2004 WL 3327264, CV 03-4227 LDW WDW at *6 (E.D.N.Y. Dec 16, 2007).

6. Dr. Kovak objects to the Subpoena to the extent that it seeks documents which are already in the possession of Candela Corporation and which are therefore available to Candela Corporation at equal or less burden than to Dr. Kovak.

7. Dr. Kovak objects to the Subpoena to the extent that it purports to impose obligations on Dr. Kovak beyond those set forth in, or exceeds the scope of discovery permitted under, the Federal Rules of Civil Procedure or any other rules applicable to this action.

8. Dr. Kovak objects to the Subpoena to the extent that it purports to call for production of documents not within Dr. Kovak's possession, custody, or control.

9. Dr. Kovak objects to the Subpoena to the extent that it seeks documents that do not concern claimed methods or devices of the patents-in-suit, and otherwise to the extent it calls for production of documents which are irrelevant, immaterial, not reasonably calculated to lead to the discovery of admissible evidence, or not germane to any claim or defense in this action.

10. Dr. Kovak objects to the Subpoena on the basis that Dr. Kovak's reputation, medical practice, related business, and livelihood all would be irreparably damaged if any of his patients learned that their medical records, particularly clinical photographs, were disclosed to other parties without consent.

SPECIFIC OBJECTIONS

Definitions

1 & 2. Dr. Kovak objects to the definitions of the term "document" to the extent that they exceed the scope of, or would impose any greater obligation on Dr. Kovak, than the requirements of the Federal Rules of Civil Procedure. Moreover, Dr. Kovak objects to the definitions of the term "document" to the extent the definitions include clinical photographs because, in many instances, it would be impossible to redact clinical photos requested by Candela Corporation to sufficiently obscure the identity of Dr. Kovak's patients.

3. Dr. Kovak objects to the instruction contained in this paragraph because, *inter alia*, the current protective order in this lawsuit is insufficient, as it does not contain any reference to HIPAA and does not specifically address medical records or patient information.

4 - 7. Dr. Kovak objects to the definitions contained in these paragraphs to the extent that they exceed the scope of, or would impose any greater obligation on Dr. Kovak, than the requirements of the Federal Rules of Civil Procedure.

8 & 9. Dr. Kovak objects to the definitions contained in these paragraphs because they are vague, overbroad, and impose an undue burden on Dr. Kovak to determine the identity of each and every individual and entity referenced in these paragraphs.

11. Dr. Kovak objects to the definition of the term "Wrinkle Treatment" because it is vague, overbroad, and to the extent that it describes methods that do not involve the patents-in-suit or otherwise describes matters that are irrelevant, immaterial, or not germane to any claim or defense in this action.

12. Dr. Kovak objects to the definition of the term "Relevant Product" to the extent it seeks information regarding products that are not formally accused of infringement in this action or otherwise describes matters that are irrelevant, immaterial, or not germane to any claim or defense in this action.

13. Dr. Kovak objects to the definition of the term "Marketing/Seminar Materials" because it is vague, overbroad, and to the extent that it describes matters that are irrelevant, immaterial, or not germane to any claim or defense in this action. In addition, Dr. Kovak objects to this definition to the extent that it describes documents which are already in the possession of Candela Corporation and which are therefore available to Candela Corporation at equal or less burden than to Dr. Kovak.

14. Dr. Kovak objects to the definition of the term "Lux Club Materials" because it is vague and to the extent that it describes matters that are irrelevant, immaterial, or not germane to any claim or defense in this action. In addition, Dr. Kovak objects to this definition to the extent

that it describes documents which are already in the possession of Candela Corporation and which are therefore available to Candela Corporation at equal or less burden than to Dr. Kovak.

15. Dr. Kovak objects to the definition of the term "Palomar Doctor" because it is vague, overbroad, and imposes an undue burden on Dr. Kovak to determine the identity of each and every individual who is described therein.

16. Dr. Kovak objects to the definition of the term "Treatment Plan" because it is vague, overbroad and to the extent that it describes matters that are irrelevant, immaterial, or not germane to any claim or defense in this action.

17. Dr. Kovak objects to the definition of the term "Training Materials" because it is vague and to the extent that it describes matters that are irrelevant, immaterial, or not germane to any claim or defense in this action. In addition, Dr. Kovak objects to this definition to the extent that it describes documents which are already be in the possession of Candela Corporation and which are therefore available to Candela Corporation at equal or less burden than to Dr. Kovak. Moreover, Dr. Kovak objects to this term because it imposes an undue burden on Dr. Kovak to determine the identity of each and every individual who is described therein.

18. Dr. Kovak objects to the definition of the term "Sponsored Events" because it is vague, overbroad and to the extent that it describes matters that are irrelevant, immaterial, or not germane to any claim or defense in this action. In addition, Dr. Kovak objects to this term because it imposes an undue burden on Dr. Kovak to determine, *inter alia*, what event(s) Palomar paid for or sponsored, and to determine the identity of each and every individual who is described therein.

20. Dr. Kovak objects to the definition of the term "Customer" because it is vague, overbroad and it imposes an undue burden on Dr. Kovak to determine, *inter alia*, the identity of each and every individual and entity who is described therein.

21. Dr. Kovak objects to the definition of the term "Patient" because it is vague, overbroad and it imposes an undue burden on Dr. Kovak to determine, *inter alia*, the identity of each and every individual who is described therein.

22. Dr. Kovak objects to the definition of the term "Recipient" because it is vague, overbroad, it seeks to impose a greater obligation on Dr. Kovak than the requirements of the Federal Rules of Civil Procedure, and it disregards any corporate form.

Instructions

1. Dr. Kovak objects to this instruction to the extent that it implies that the Amended Protective Order is sufficient to cover medical records and patient files despite the fact that it

does not contain any reference to HIPAA and does not specifically address medical records or patient information.

2. Dr. Kovak objects to this instruction to the extent that it purports to call for production of documents not within Dr. Kovak's possession, custody, or control. Moreover, Dr. Kovak objects to the extent that this instruction generally exceeds the scope of, or would impose any greater obligation on Dr. Kovak, than the requirements of the Federal Rules of Civil Procedure. Dr. Kovak also objects to this instruction because it requests clinical photographs that, in many instances, are impossible to redact sufficiently obscure the identity of Dr. Kovak's patients.

3. Dr. Kovak objects to this instruction to the extent that it exceeds the scope of, or would impose any greater obligation on Dr. Kovak, than the requirements of the Federal Rules of Civil Procedure.

Document Requests

1. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, unduly burdensome, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Dr. Kovak further specifically objects to this request on the ground that it seeks the production of documents protected by the attorney-client privilege, the work product privilege, or any other applicable privilege.

2. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Dr. Kovak further specifically objects to this request on the ground that it is overly broad and imposes an undue burden on Dr. Kovak because it, *inter alia*, requires him to determine what, if any, materials were shown to particular patients or potential patients. the identity of each and every individual and entity referenced in this request. In addition, Dr. Kovak further specifically objects to this request on the ground that it seeks documents which have already been produced in the lawsuit or otherwise are already in the possession of Candela Corporation and which are therefore available to Candela Corporation at equal or less burden than to Dr. Kovak.

3. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Dr. Kovak further specifically objects to this request on the ground that it imposes an undue burden on Dr. Kovak because it, *inter alia*, requires him to determine the identity of each and every individual and entity referenced in this request.

4. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Dr. Kovak further specifically objects to this request on the ground that it imposes an undue burden on Dr. Kovak because, *inter alia*, it requires him to determine the identity of each and every individual and entity referenced in this request. In addition, Dr. Kovak further specifically objects to this request on the ground that it seeks confidential medical records and patient files.

5. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Dr. Kovak further specifically objects to this request on the ground that it imposes an undue burden on Dr. Kovak because, *inter alia*, it requires him to determine the identity of each and every individual referenced in this request. In addition, Dr. Kovak further specifically objects to this request on the ground that it seeks confidential medical records and patient files (including clinical photographs which, in many instances, cannot be redacted to sufficiently obscure the identity of Dr. Kovak's patients).

6. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, unduly burdensome, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. In addition, Dr. Kovak further specifically objects to this request on the ground that it seeks confidential medical records and patient files (including clinical photographs which, in many instances, cannot be redacted to sufficiently obscure the identity of Dr. Kovak's patients).

7. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, unduly burdensome, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence.

8. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, unduly burdensome, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. In addition, Dr. Kovak objects to this request to the extent that it seeks documents which have already been produced in the lawsuit or otherwise are already in the possession of Candela Corporation and which are therefore available to Candela Corporation at equal or less burden than to Dr. Kovak. In addition, Dr. Kovak further specifically objects to this request on the ground that it seeks confidential medical records and patient files (including clinical photographs which, in many instances, cannot be redacted to sufficiently obscure the identity of Dr. Kovak's patients).

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9. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. Moreover, Dr. Kovak further specifically objects to this request on the ground that it imposes an undue burden on Dr. Kovak because, *inter alia*, it requires him to determine the identity of each and every individual referenced in this request. In addition, Dr. Kovak further specifically objects to this request on the ground that it seeks confidential medical records and patient files.

10. Dr. Kovak further specifically objects to this request on the grounds that it is vague, ambiguous, overly broad, unduly burdensome, and seeks information that is neither relevant to any claim or defense in this action nor reasonably calculated to lead to the discovery of admissible evidence. In addition, Dr. Kovak further specifically objects to this request on the ground that it seeks documents which have already been produced in the lawsuit or otherwise are already in the possession of Candela Corporation and which are therefore available to Candela Corporation at equal or less burden than to Dr. Kovak.

Please note that, in light of the above objections, Dr. Kovak does not intend to produce or permit inspection or copying of documents or other information at the scheduled deposition on December 20, 2007. Please contact me immediately if Candela Corporation intends to convene the deposition notwithstanding these objections and this notice, as Dr. Kovak will take other action as is necessary to protect his rights.

Sincerely,

Stephen D. Riden

cc: Timothy Cleveland, Esq.

Exhibit 4

MCKOOL SMITH
A PROFESSIONAL CORPORATION • ATTORNEYS
300 West 6th Street
Suite 1700
Austin, Texas 78701

Craig N. Tolliver
Direct Dial: (512) 692-8738
ctolliver@mckoolsmith.com

Telephone: (512) 692-8700
Telecopier: (512) 692-8744

December 24, 2007

VIA EMAIL

John T. Gutkoski, Esq.
Foley & Lardner, LLP
111 Huntington Avenue
Boston, Massachusetts 02199

RE: *Candela Corporation v. Palomar Medical Technologies, Inc.*

Dear John:

I am writing to summarize our meet and confer teleconference from Friday, December 21, regarding the subpoenae recently served by Plaintiffs on certain third-party physicians. The meet and confer was attended by Stephen Riden and you on behalf of the third-party physicians, and John Shumaker, Laura Handley, and me on behalf of Plaintiffs. The purpose of the teleconference was to determine, for the eighteen[1] individuals that your firm represents, whether they would voluntarily agree to produce any documents in response to Plaintiffs' subpoenae. This meet and confer was necessitated by the fact that each of your eighteen clients provided Plaintiffs with boilerplate objections to Plaintiffs' subpoenae document requests and seventeen of them refused to produce a single document in response to the subpoenae. Plaintiffs were hopeful that if you were able to explain your clients' concerns during the meet and confer, the parties could reach agreement on a document production by your clients without the need for motion practice.

Your Clients' Method of Maintaining Records

You advised that your clients' primary concern was the manner in which they maintained their records. Specifically, you advised that, prior to our December 21 teleconference, your firm spoke with each and every one of the third-party physicians regarding the manner in which their records were maintained, and that each and every one told your firm that they did not have any mechanism to determine what Palomar accused device (or any other device) the physicians may have used with any patient, or how many times total the physicians had used a Palomar device. In short, you stated that each and every one of the subpoenaed individuals specifically told you that their records were in paper format and organized by patient only, so that they would have to search each and every patient record in order to locate documents responsive to several of the ten

[1] Our records indicate that Foley represents seventeen of the third-party physicians for purposes of responding to the subpoenae, while the Beck, Redden firm represents one third-party physician. Mr. Cleveland of Beck, Redden, did not attend the call but you stated that your clients' interests were aligned with his client's interests, so his absence was not of concern.

document categories included in Plaintiffs' requests. You stated, for example, that each of those individuals told your firm that they did not have any database or spreadsheet that would allow them to perform a sort function by Palomar device or treatment-type (for example, wrinkle reduction).

I expressed my surprise that each of the eighteen third-party physicians would maintain their records in a manner that would preclude them from determining what treatments had been performed by the physician. For example, I raised a hypothetical where Palomar (or some other company) issued an advisory to one of your clients regarding problems experienced with a particular aesthetic laser device, and requested that one of your clients contact all of his/her patients who had used that device in order to ensure the patients' safety. According to your explanation of how your clients maintain records, your clients would be unable to identify what patients they had treated with that device, and thus would be unable to perform the safety follow-up investigation, short of reviewing by hand every single patient file.

Nevertheless, you agreed to follow up with your clients on a few issues. First, you stated that you had not asked your clients whether they could use billing codes to determine what products had been used (e.g., Palomar accused products) or what procedures had been performed (e.g., wrinkle reduction) by that client. You agreed to follow up on that.

Second, you stated during the call that "some" of your clients told your firm that they did not bill according to treatment performed or product/device used. However, you were not able to identify which clients said that, and did not know whether the other clients (i.e., other than the "some") stated that they *did* bill according to treatment performed or produce/device used, or whether they just were not asked about that issue in the first place. You agreed to consult your notes and let me know, and, as stated above, to follow up with your clients to determine whether their billing methods could be used to assist with the identification of responsive documents.

Discussion Regarding Individual Document Categories

We discussed each of the categories of requested documents found in Plaintiffs' subpoenae. During this discussion, Plaintiffs proposed ways to narrow the categories so that you could determine whether your clients' would agree to produce documents without the need for motion practice before the courts.

General Issue (Wrinkle Treatment): One issue that arose with respect to multiple categories was the term "wrinkle treatment," which appears as a limitation in several of the categories. I explained that the term "wrinkle treatment" was added to the requests in an effort to minimize the burden to your clients so that instead of simply producing documents relating to the Palomar accused devices, they could produce only documents relating to a Palomar accused device being used for wrinkle treatment.

Even if your clients truly are confused by the definition of "wrinkle treatment," it is improper for your clients to fail to produce the documents that they understand to be responsive. After your clients produce responsive documents, you can advise us as to the documents they intend to withhold based on their understanding of "wrinkle treatment" yet are somehow

confused about, and we can address that issue separately. If your clients would prefer to remove the "wrinkle treatment" qualification altogether and produce responsive documents related to the Palomar accused devices (regardless of the treatment being performed), they may do so. Alternatively, if your clients believe that a modified definition would allow them to produce responsive documents more easily, please advise us of that proposed modification. The bottom line is that your clients' apparent confusion as to what is meant by "wrinkle treatment" is not a good reason to hold up your clients' document production.

Category 1: Your clients provided boilerplate privilege/work product objections. However, you admitted that one or more of your clients "possibly" could have documents responsive to this category but you did not know who might have such documents, although you estimated that such person probably would not have many such documents. I expressed my concern that, based on our discussion, it did not appear that your firm had adequately discussed this category with your clients because you did not know which clients may have responsive documents. Moreover, if one or more of your clients had some small number of responsive documents, there is no reason they should be withholding those documents or a privilege log related to those documents. You stated that it would make sense to withhold documents responsive to this category because your clients had objected to other categories and if a motion to compel would be required for the other categories, then we "might as well move on all the categories at once." Plaintiffs disagree that this is a proper reason to withhold documents responsive to Category 1.

Nevertheless, Plaintiffs agreed that if your clients agree to produce an acceptable collection of documents, your clients could limit the date range of this category to the time period spanning from the time this lawsuit was filed in 2006 up until the time that your firm began representation of the third-party physicians. The latter date limitation was discussed so that your clients would not need to log communications between your clients and your firm subsequent to your representation of them.

We look forward to hearing from you as to why any of your clients withheld documents responsive to this category, and whether they will now provide responsive documents and a privilege log for any withheld documents.

Category 2: You advised that each and every one of your clients apparently could not determine whether they had the marketing documents called for by this category without undue burden because, in addition to the "wrinkle treatment" issue (see above), they could not tell whether the material was "actually presented to or viewed by an actual or potential patient." Plaintiffs agreed to remove this limitation in order to relieve your clients' confusion.

Further, Plaintiffs agreed that if your clients agree to produce an acceptable collection of documents, your clients could limit the date range of this category to the time period subsequent to and including January 1, 2006. You agreed to check with your clients as to whether they will now provide responsive documents.

Category 3: Other than the "wrinkle treatment" issue (see above), you identified only a potential issue regarding the date range of this category. Accordingly, Plaintiffs agreed that if

your clients agree to produce an acceptable collection of documents, your clients could limit the date range of this category to the time period subsequent to and including January 1, 2006. You agreed to check with your clients as to whether they will now provide responsive documents.

Category 4: You advised that each and every one of your clients would be unable to locate responsive documents without undue burden because of the manner in which they maintain their files and because of the "wrinkle treatment" issue. Both of these issues are discussed above. You agreed to check with your clients as to whether they will now provide responsive documents. For example, you agreed that you would check with your clients to determine if their billing systems, including billing codes, could you used to identify responsive documents.

Category 5: Again, you advised that each and every one of your clients advised that they would be unable to locate responsive documents without undue burden because of the manner in which they maintain their files and because of the "wrinkle treatment" issue. Both of these issues are discussed above.

Plaintiffs also provided further clarification of this category, in an attempt to reach agreement with your clients. First, Plaintiffs advised that they do not intend for your clients to produce raw photographs in response to this category. Instead, as already stated in the subpoenae category, responsive documents would need to include an "evaluation," such as a numerical estimate as to the amount of wrinkle reduction shown, a written assessment or description of wrinkle reduction, or feedback from a patient. Second, Plaintiffs again agreed that if your clients agree to produce an acceptable collection of documents, your clients could limit the date range of this category to the time period subsequent to and including January 1, 2006. You agreed to check with your clients as to whether they will now provide responsive documents.

Category 6: Again, you advised that each and every one of your clients advised that they would be unable to locate responsive documents without undue burden because of the manner in which they maintain their files. This issue is discussed above.

Plaintiffs also pointed out that this category does not call for photographs where a patient is simply being shown his or her own before/after photographs. Instead, as the request states, the photographs are being requested only where the photographs are being used for some other purpose (such as marketing or in presentations). Plaintiffs again agreed that if your clients agree to produce an acceptable collection of documents, your clients could limit the date range of this category to the time period subsequent to and including January 1, 2006. You agreed to check with your clients as to whether they will now provide responsive documents.

Category 7: In the interest of cooperation, Plaintiffs agreed to withdraw this document category in its entirety if your clients agree to produce an acceptable collection of documents responsive to the other categories.

Category 8: You advised that each and every one of your clients advised that they would be unable to locate responsive documents without undue burden because they would be

required to comb through each of their hardcopy patient files to locate responsive FDA-related documents. You further advised that your clients would not be able to determine whether any particular data or documents were related to an FDA study because your clients may not have known at the time that they were obtaining information for an FDA study.

In response, I stated that it simply did not seem correct to say that your clients may be performing FDA-related studies for Palomar without knowing that they are doing so. At a minimum, the patients participating in an FDA study should have signed an informed consent form identifying the risks associated with the study. As such, it seemed likely that your clients would maintain their FDA-related documents in files separate from the client files. You agreed to look into this issue with your clients, and then more specifically advise as to why your clients allegedly would be unable to produce their FDA-related documents.

Category 9: Again, you advised that each and every one of your clients advised that they would be unable to locate responsive documents without undue burden because of the manner in which they maintain their files and because of the "wrinkle treatment" issue. Both of these issues are discussed above.

Plaintiffs again agreed that if your clients agree to produce an acceptable collection of documents, your clients could limit the date range of this category to the time period subsequent to and including January 1, 2006. You agreed to check with your clients as to whether they will now provide responsive documents.

Category 10: Plaintiffs advised that this category may be considered to be specific examples of the types of documents called for by Categories 2 and 3, discussed above.

Payment for Copies

As advised during the teleconference, if your clients agree to produce responsive documents, Plaintiffs will make payment for copies of documents they may wish to obtain.

Dr. Zelickson's Documents

You advised that Dr. Zelickson will voluntarily produce some limited number of documents. However, you did not know how many documents he would produce, or when. We look forward to receiving his documents as soon as possible. Please let us know when Dr. Zelickson will be producing his responsive documents.

January 11 Deadline for Response

As stated during our teleconference, Plaintiffs are cognizant of the upcoming holiday season, but cannot allow undue delay before hearing back from you in response to the issues stated above. Plaintiffs are prepared to file motions to compel if the parties are unable to voluntarily agree on an acceptable production of documents. Accordingly, please respond to the issues discussed above **no later than Friday, January 11, 2008**, and if your clients will be producing responsive documents, please advise when Plaintiffs will receive those documents. If

you do not provide a satisfactory response by that date, Plaintiffs promptly thereafter will move to compel your clients' documents in the appropriate jurisdictions.

Please note that your clients provided objections to their subpoenae within approximately ten days after the subpoenae were issued, and therefore you presumably were able to engage in detailed discussions with each of your clients within that timeframe. Therefore, the January 11 deadline should be more than enough time to respond to the above-referenced issues which should be much narrower than the issues you needed to discuss with your clients to prepare your subpoenae objections.

Plaintiffs are hopeful that your clients will not persist in their unreasonable decision to withhold every single responsive document in their possession, and that Plaintiffs' attempts at compromise, made during the December 21 meet and confer, will encourage your clients to produce documents without the need for motion practice. Please let me know if you have any questions.

Sincerely,

/s/ Craig Tolliver

Craig N. Tolliver

Exhibit 5

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FOLEY & LARDNER LLP

ATTORNEYS AT LAW
111 HUNTINGTON AVENUE
BOSTON, MASSACHUSETTS 02199
617.342.4000 TEL
617.342.4001 FAX
www.foley.com

WRITER'S DIRECT LINE
617.342.4078
srlden@foley.com EMAIL

CLIENT/MATTER NUMBER
090577-0101

January 11, 2008

VIA E-MAIL AND U.S. MAIL

Craig N. Tolliver, Esquire
McKool Smith
300 West 6th Street, Suite 1700
Austin, TX 78701

RE: *Candela Corporation and Massachusetts General Hospital v. Palomar Medical Technologies, Inc.*, Civ. Action No. 9-06-CV-277-RHC

Dear Craig:

I am in receipt of your letter of December 24, 2007. In your letter, you purport to summarize our meet and confer telephone conference of December 21, 2007 concerning plaintiffs' subpoenas to the third-party physicians.

As a threshold matter, it bears repeating that the targets of plaintiffs' subpoenas are all nonparties, they have no individual stake in this litigation, and your clients demands for their time and documents represent a considerable and undue burden on them. Thus, while plaintiffs have offered to narrow the scope of the subpoenas in some respects, the remaining requests, when taken together, still represent a considerable imposition on these physicians and their medical practices.

Addressing, first, your contentions about the physicians' maintenance of records, as we noted in the objections to your subpoenas, Candela's requests are objectionable because they are, *inter alia*, broadly written to encompass all documents that show how many times the physician used "the Relevant Product for any Wrinkle Treatment." As you know, our clients are physicians. As much, they maintain their records in a manner that is consistent with the treatment of individual patients. As we explained and as your letter notes, in order to respond to your subpoenas, doctors with potentially responsive documents would need to personally review by hand numerous patient files. In apparent recognition of the improper burden imposed upon the physicians by your requests, we understand plaintiffs are now focusing on obtaining copies of documents that contain treatment data in summary or abstract form. To that end, we have agreed to follow up with our clients concerning plaintiffs' new, narrower requests for such information.

Your letter specifically misstates our clients' objections regarding the subpoenas' use and definition of the term "Wrinkle Treatment" and similar terms. The issue is not only one of confusion due to plaintiffs' lack of precision. Additionally, it is the breadth of the definition. It arguably could include just about any skin treatment employing Electromagnetic Radiation. It

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also employs terms such as "photofacial" and "photorejuvenation" that may have different meanings to different people in this industry. Plaintiffs' use of such a definition is overly broad and would subject the physicians to undue burden.

Your letter misstates our explanation regarding Category 1, to which we understand that our third-party physician clients have no responsive documents. Employing the new date restrictions, in your letter, we will confirm whether any exist.

We also do not understand your letters' references to "if your clients agree to produce an acceptable collection of documents."

Other than Category 1, each of the subpoenas' categories employ improper and overly broad "Wrinkle Treatment" definitions, as noted above. For the interest of cooperation, however, and as promised in our call, we are in the process of collecting information from our physician clients, and – without waiving any general or specific objections to plaintiffs' subpoenas – we are determining whether summary, abstract or other documents exists to enable our physician clients to review their records in a manner that is not unduly burdensome. If such is the case for any of the physicians, any existing documents will be produced in response to plaintiffs' latest form of subpoenas, as modified during our phone call of December 21, 2007, as they are identified and subject to any of the physicians' remaining objections.

In response to Candela's subpoena to Brian Zelickson, MD, documents from Dr. Zelickson will be produced next week.

Finally, there is no basis for you to characterize our clients' response to plaintiffs' subpoenas as "unreasonable" – as their approach is an appropriate response to plaintiffs' burdensome discovery requests. Plaintiffs have already conceded the overly broad and burdensomeness of their discovery letters toward these third-party physicians by issuing, but then withdrawing, in full, their initial subpoenas to the physicians. Plaintiffs' reissued subpoenas continue to suffer from any of the same infirmities as the initial versions, and still, as we have discussed at length, thereto imposing significantly on the practices of these physicians. For plaintiffs now to threaten motion practice to compel these nonparties to comply with overly broad subpoenas only compounds plaintiffs' oppression.

Sincerely,

Stephen D. Riden

cc: Timothy Cleveland, Esq.

Exhibit 6

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
LUFKIN DIVISION

CANDELA CORPORATION, ET AL	*	DOCKET 9:06CV277
	*	1:30 P.M.
V.	*	
	*	MARCH 23, 2007
PALOMAR MEDICAL TECHNOLOGIES, INC.	*	BEAUMONT, TEXAS

VOLUME 1 OF 1, PAGES 1 THROUGH 44
REPORTER'S TRANSCRIPT OF CASE MANAGEMENT CONFERENCE
BEFORE THE HONORABLE RON CLARK
UNITED STATES DISTRICT JUDGE

FOR THE PLAINTIFFS CANDELA CORPORATION AND MASSACHUSETTS GENERAL HOSPITAL:

SAMUEL FRANKLIN BAXTER
M. JILL BINDLER
MCKOOL SMITH
300 CRESCENT COURT, SUITE 1500
DALLAS, TEXAS 75201

FOR THE PLAINTIFF CANDELA CORPORATION:

HOWARD S. SUH
KAYE SCHOLER
425 PARK AVENUE
NEW YORK, NEW YORK 10022-3598
PAUL R. LUCCHESE
(CANDELA CLIENT REPRESENTATIVE)

PAUL CUSHING
FRANCES TONEGUZZO
(MASS. CLIENT REPRESENTATIVES)

Page 18

MR. SUH: We are not aware of actually notice letters, your Honor; but we are aware of conversations that took place at least eight to nine months prior to the filing of the lawsuit where specific discussions were had between the parties regarding these patents.

THE COURT: In terms of possible licensing or, "We think you're infringing. Stop"? I mean, what kind of conversations?

MR. SUH: In the context of licensing.

THE COURT: Okay. All right. Let me ask defendants, then, basically the flip side of some of these questions.

MR. BECK: Your Honor, it may be more efficient if Mr. Gutkoski speaks directly to the court.

THE COURT: That's fine. Or, actually, one of you could be at one microphone and one at the other. Handle it any way you want.

Based on what you know so far -- and you've heard some this morning, and presumably you are somewhat aware of their devices if they are out on the market -- do you think the main thrust here is going to be noninfringement; or do you think this is such an obvious, anticipated thing that that's really going to be your main thrust? And, again, I'm not trying to bar you from using one or the other; but I'm trying to get an idea of where we'll be going.

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MR. GUTKOSKI: We're going to be going down both roads, your Honor.

THE COURT: Well, I understand that. Every defendant always does. But, you know, do you really think that -- for example, give me some indication of something that your device does or some part of the method that you think is not what theirs is. How is your product different from theirs or your method different from theirs?

MR. GUTKOSKI: Well, let me preface this, your Honor, with -- we've had identified here in court today various products which are not asserted in the complaint.

THE COURT: Well, pick some of the ones that were asserted --

MR. GUTKOSKI: I just note that for the first time we are hearing that there will be accused in this lawsuit various products, including the IRE and B and G --

THE COURT: Think of all the discovery time I've saved you.

MR. GUTKOSKI: It's much appreciated; and don't think it's not, your Honor.

Your Honor, the Lux1540, which was asserted in the complaint and listed today, in fact, doesn't practice any of the methods set forth in the claims because it --

THE COURT: Well, how does it get rid of wrinkles; or doesn't it -- it's not a wrinkle device?

Page 20

MR. GUTKOSKI: It is not approved for wrinkles right now, your Honor.

THE COURT: What is it approved for?

MR. GUTKOSKI: It is approved for various other skin treatments, but it is not approved -- does not have FDA approval for wrinkles as we sit right here, your Honor.

The operation of the 1540 is actually a very different device. It's the next generation of these type of devices. It's what's called a fractional system. It divides the laser beam that comes out of the base unit into a number of microbeams. None of these are discussed in the method claims. It operates on the skin in a completely different way than what is described in the method claims, and its operation is very different from what is described in their apparatus claims.

So, on the noninfringement side, your Honor, we believe we have several distinctions, several different aspects of the claims, both in terms of the laser itself, how it's defined, its wavelength, its power density, et cetera, as well as what it does to the skin, what it does to the collagen, which are points of distinction.

THE COURT: Well, now, of course, I think I'm correct that I've seen cases that held that just because someone advances some technology but still winds up -- they could still be infringing if they are using the basic underlying technology anyway. So, simply to say that this is

Page 21

an advance doesn't necessarily mean it doesn't infringe.

I mean, are you using -- the first two patents we talked about, I think, had a pretty set band of wavelengths, at least on some of the method claims. Is yours using different wavelengths, or is there some other thing that's different?

MR. GUTKOSKI: Not different wavelengths, your Honor; but the fluence, the energy involved, the energy density, those are different. Depending upon which claims actually get asserted, the laser parameters are defined in different ways. Some talk in terms of fluence. Some talk in terms of energy density. We believe that our product -- in particular, the 1540 -- has different laser parameters that do not fall within the claims.

THE COURT: Now, theirs talk in terms of -- what is it -- injuring -- yeah, thermally injuring the collagen, which evidently they believe results in the body filling it back in or bringing in more or -- I mean, it goes into some detail there. But is that, or is that not, the basic mechanism of -- I mean, you may reach it a different way; but is that what your device winds up doing, that somehow it causes this -- and "injury" is probably not the best word, but it is the one that the patentee chose. It causes some action or reaction that winds up with the body then reacting to try to heal -- maybe, in quotation marks, fill in -- resulting in a plumping out of the skin. And, again, I have not studied these in great

Exhibit 7

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DIVISION OF TEXAS
LUFKIN DIVISION

CANDELA CORPORATION,	
Plaintiff,	
vs.	**Civil Action No. 9-06-CV-277-RHC**
PALOMAR MEDICAL TECHNOLOGIES, INC.	
Defendant.	

DEFENDANT PALOMAR MEDICAL TECHNOLOGIES, INC.'S CLAIM CONSTRUCTION BRIEF

collagenases, however, is precisely the "aggressive healing response" from the prior art that the patents said would not work to treat wrinkles and was to be avoided. (Col. 2:37-44.)[13]

Plaintiffs rely on a degradation of collagen reference in the Experimental Results section of the patents. (*See* Pl. Br. at 13.) The Experimental Results section, however, does not describe embodiments of the claimed inventions or the practicing of any such inventions. The Experimental Results section describes rudimentary experiments trying various combinations of parameters, causing varying degrees of injuries with varying results. (Col. 6:54 – 7:3.) The patents disclose neither which parameter combinations were "appropriate," nor those which resulted in which injuries or results. (*See id.*) Moreover, although the claims of the patents are directed to "treating a wrinkle in human skin," the Experimental Results section all involved tests "performed on pigs," (col. 6:36-38). In addition, none of the Experimental Results claim to have had any impact on wrinkles, and certainly do not result in the production of "substantially unwrinkled skin" as required by all of the claims. Therefore, plaintiffs' attempt to use the elementary experiments described in the Experimental Results section to broaden what is claimed by the patents and taught by their specification is inappropriate.[14]

B. **"that produces substantially unwrinkled skin"**

[redacted]

[13] Plaintiffs also attempt to buttress their proposed construction by claiming it is "harmonious" with statements made during prosecution concerning a PCT publication to Hennings and Sand. (*See* Pl. Br. at 13-14.) Reliance on these representations, however, is disingenuous, because both the statements made now by plaintiffs and those made during prosecution directly contradict the statements contained in the specification of the Hennings and Sand publication, as well as the way the plaintiffs described Hennings and Sand in plaintiffs' own patents. (*See* Palomar's Answer to Plaintiffs' Second Amended Complaint (Docket # 61), Seventh Affirmative Defense.)

[14] Notably, plaintiffs do not attempt to explain how the inventions can include the degradation of existing collagen when the specification expressly states that causing such degradation will not work to treat wrinkles in human skin. (*See* Col. 2:36-44; Pl. Br. at 13.)

"substantially unwrinkled skin" '801 patent, claims 4-5, 9-11, 14; '497 patent, claims 1-10; '999 patent, claims 1-10.	"skin having a reduction in the number or size of wrinkles."	"skin from which substantially all of the wrinkle has been removed to produce smooth skin"
"produces substantially unwrinkled skin" '801 patent, claims 1-6, 8-14; '497 patent, claims 1-10; '999 patent, claims 1-10.	Phrase does not require separate construction, in view of the terms therein, plus plain meaning. See Plaintiffs' construction of "substantially unwrinkled skin."	"removes substantially all of the wrinkle to produce smooth skin"

Plaintiffs' construction seeks to broaden this limitation in three impermissible ways. First, plaintiffs propose a definition of "substantially" that the Federal Circuit has expressly rejected. Second, they ignore the actual words in the claims that "substantially" modifies: "unwrinkled skin." Third, plaintiffs improperly attempt to use the specification to expand the specific results that the patents actually claim.

Plaintiffs propose construing "substantially" to mean "having a reduction in" so that any measurable or quantifiable amount would qualify as "substantial."[15] The Federal Circuit has expressly rejected such a construction, and has held that the ordinary meaning of "substantially" is "considerable in extent" or "largely but not wholly that which is specified". *York Products v. Central Tractor Farm & Family Center*, 99 F.3d 1568, 1572-73 (Fed.Cir. 1996) (emphasis supplied). Placing the Federal Circuit's definition of "substantially" into the claim language of the patents yields: "producing [considerably] unwrinkled skin" or "producing [largely but not wholly] unwrinkled skin." Accordingly, the ordinary meaning of "produces substantially

[15] Indeed, plaintiffs' proposed construction would lead to the odd conclusion that, for example, a mere 1-2% reduction in the size or number of wrinkles would qualify as "substantial." Patients frequently pay thousands of dollars for laser skin treatments and none would be content with such a poor level of improvement. (Bass Decl. ¶13.) Moreover, such minimal improvement would not be consistent with addressing "the types of problems encountered in the art," *Rulz*, 234 F.3d at 666-67.